

SCIENCE AND TECHNOLOGY COMMITTEE

Fourth Report

**THE REGULATION OF THE
BIOTECHNOLOGY INDUSTRY**

Report, Minutes of Proceedings, Minutes of Evidence
and Appendix

*Ordered by The House of Commons to be printed
27 October 1999*

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SCIENCE AND TECHNOLOGY COMMITTEE

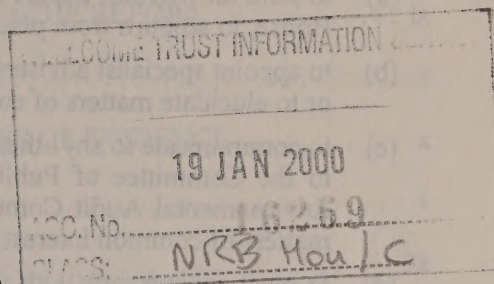
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FOURTH REPORT

The Science and Technology Committee has agreed to the following Report:—

THE REGULATION OF THE BIOTECHNOLOGY INDUSTRY

1. The BioIndustry Association (BIA) published its draft Code of Best Practice for the biotechnology industry in July 1999. We took oral evidence from both the BIA and the London Stock Exchange on 2nd September and subsequently submitted the following comments to the BIA.

“The Science and Technology Committee welcomes the BioIndustry Association’s draft Code of Best Practice regarding the management of information and intelligence. We are pleased to be able to comment on the draft Code and, in particular, grateful for the opportunity to discuss the Code and its contents with you and your colleagues before doing so.

In its Report on British Biotech,¹ the Committee pointed out that “in an environment where subjective judgements and sentiment are so important in determining share price and company value, and where investors are to a large degree dependent upon the company to inform those judgements, the accuracy, precision and objectivity of information released is vital”. It also recommended, *inter alia*, that “all biotechnology companies ... make full use of external scientific expertise and advice” and that “biotechnology companies should be able to call upon appropriate expertise for all areas of company activity and strive to reach a balance among their non-executive directors between those who can offer crucial business development expertise and those who are familiar with the risks and vicissitudes of drug development”. We are pleased to note that these considerations have formed the basis on which the draft Code of Practice has been developed.

In general we endorse the draft Code of Practice and support its introduction; we understand that the Stock Exchange does too. We are aware that it can have little impact on the behaviour of those companies which are determined to ignore best practice and to manage their affairs in a manner best suited to the maintenance of share price and company value regardless. The Code does, however, have considerable and significant merit, first in terms of alerting company managers and directors to the difficulties inherent in news and information management in this the biotechnology industry and, secondly, by providing guidance which may prevent unintentional deviations from established best practice. Our major concern is not so much over the principles and provisions of the Code itself but over the way in which the BioIndustry Association intends to implement it.

We are disappointed that no formal mechanism for monitoring compliance with the Code is to be established and believe that this will significantly limit its effectiveness. Monitoring need not be a complicated or onerous activity: it could be done simply by selecting a small random sample from among the companies which claim to adhere to the Code, say once a year, and asking them to state what they have done to ensure compliance with the Code and what they understand compliance to mean. The BioIndustry Association could then check the returns. Nor would this impose any additional burden on the companies concerned as all those complying with the Code are expected to make a similar statement in their annual financial reports. There is also an onus on the investment community and analysts to apply a more informal method of monitoring, especially in relation to those public companies which claim to adhere to the Code. Given their high levels of expertise and sector specific information, in some circumstances it will be immediately apparent to many investors and company analysts alike, should a company diverge from the principles of the Code. The BioIndustry Association could therefore increase the effectiveness of the Code by encouraging these people to report such occasions. Indeed, many may be most willing to do so given that widespread compliance with the Code could serve to reduce the risk associated with investment in their sector.

The Code will only apply to those bioscience companies which are members of the BioIndustry Association. Adherence to the Code could, however, become a key factor in investment decisions, as the Stock Exchange told us, for those with funds to invest in the biotechnology

¹Fifth Report from the Science and Technology Committee, Session 1997-98, on British Biotech, HC 888.

agree on the timing of the release of price sensitive information in advance. We have amended Principle 7 accordingly.

5. On the subject of limiting companies' announcements on the regulatory process to simple statements of fact, we agree that Principle 8 in the consultation document could be made more explicit, with better advice. In particular, we agree that information should be put out at the clearly defined stages in the regulatory process, and we have amended the wording of Principle 8 to incorporate this.

I enclose a definitive copy of the Code which has now been circulated to members and which will be voted on at our Annual General Meeting on October 20th. We plan to issue a press release after the meeting confirming the adoption of the Code and will ensure that you receive a copy. The only other significant change made after considering the consultation inputs was delaying the introduction date by three months. This was as a result of comments to the effect that it would not be possible to have the systems in place to report compliance so soon after the Annual General Meeting. However, we have added a sentence encouraging those publishing directors' reports before the amended date to describe how they plan to comply.

If you have any further questions, please do not hesitate to contact me.

19 October 1999

Letter from the Chairman of the Committee to Dr John Sime, Chief Executive of the BioIndustry Association

I have been asked by the Science and Technology Committee to convey to you its congratulations on the adoption of the Code of Best Practice at the BioIndustry Association's Annual General Meeting. The Committee believes that the Code has the potential to become an important tool in the shaping of the biotechnology industry.

The Committee was pleased that the BIA agreed with so many of the comments it made on the draft Code and that you saw fit to make consequential amendments to the Code. It does not, however, consider these changes to be "minor", as was suggested in your press notice of 20 October. They will significantly strengthen the effectiveness of the Code.

Your press notice of 20th October, which announced that the Code had been adopted, also mentions that the Committee was consulted as part of the development of the Code. The Committee would like to point out that its role was more fundamental than such a statement implies. It is our understanding that the BIA's initiative in drawing up such a Code was stimulated by our Fifth Report of Session 1997-98 on British Biotech in which, *inter alia*, we argued that "in an environment where subjective judgements and sentiment are so important in determining share price and company value, and where investors are to a large degree dependent upon the company to inform those judgements, the accuracy, precision and objectivity of information released is vital". The Committee hopes that you will agree that its efforts during the development stage have also been significant and helpful.

The Committee will, of course, continue to monitor the implementation and effectiveness of the Code in the context of the development of the biotechnology industry in the UK. We would be most grateful if you could draw our attention to any proposed amendments to the Code over the coming months.

27 October 1999

PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT**WEDNESDAY 27 OCTOBER 1999****Members present:****Dr Michael Clark, in the Chair**

**Mr Nigel Beard
Dr Ian Gibson
Dr Lynne Jones
Mr Nigel Jones**

**Dr Ashok Kumar
Mr Ian Taylor
Dr Alan W Williams**

The Committee deliberated.

Draft Report (The Regulation of the Biotechnology Industry), proposed by the Chairman, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs Nos. 1 and 2 read and agreed to.

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Several Papers were ordered to be appended to the Report.

A Paper was ordered to be appended to the Minutes of Evidence.

Ordered, That the Appendix to the Minutes of Evidence taken before the Committee be reported to the House.

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TAKEN BEFORE THE SCIENCE AND TECHNOLOGY COMMITTEE

THURSDAY 2 SEPTEMBER 1999

Members present:

Dr Michael Clark, in the Chair

Mr Nigel Beard
Dr Ian Gibson

Dr Lynne Jones

Memorandum submitted by the BioIndustry Association

INTRODUCTION

1. The BioIndustry Association (BIA) represents small and medium sized bioscience companies. It was founded in 1989 and has over 200 members across the UK. Our members are involved in human and animal healthcare, diagnostics, environmental and, to a lesser extent, agricultural biotechnology and a growing range of non-traditional industrial applications.

Member companies are at the forefront of the industry. Many of the significant advances being made today are in the innovative SME sector represented by the BIA. There are over 460 bioscience companies in this sector of the UK economy employing an estimated 40,000 people.

The BIA represents the interests of this sector to the UK government, the European Parliament and Commission, the media, the financial community and to other stakeholders with the aim of creating a healthy UK bioscience sector which benefits society.

SUMMARY

2. The BIA is currently in the process of developing an industry Code of Practice which it plans to publish as a consultation document by the end of the first half of 1999, as previously announced. This activity limits our ability to respond more fully to the Science and Technology Committee's request for information at this time. We are grateful for the continuing interest of the Science and Technology Committee in the sector and when we reach the consultation stage of our Code of Practice we would welcome the opportunity to brief the Committee more fully on its contents.

QUESTIONS

3. *What are the key features of the regulatory regime, both in terms of the financial and pharmaceutical regulation, within which the industry operates? How was this regime developed over the last 12 months? How could it be improved?*

Bioindustry is a global business and is subject to the regulatory demands of all the countries in which it operates. For example, companies listed on both the LSE and NASDAQ have to meet the requirements of both national authorities. Equally, for a medical product to be approved in both Europe and the USA, the EMEA and US FDA requirements have to be satisfied. It is the responsibility of management to ensure they meet these various requirements.

For the purpose of this memorandum, we have provided at Annex A a brief outline of the regulatory regime within which the industry operates in the UK. As can be seen from this Annex, biotechnology companies (including companies engaged in therapeutics, diagnostics, agricultural, environmental and other life science applications) are already subject to a broad range of laws, regulations and codes. Some of these apply to all companies with shares and securities which are listed or publicly traded and others are specific to the biotechnology sector. It is our intention to include guidance on some of these laws and regulations in a specific section of the Code when it is published.

To our knowledge there have been no significant changes to this regulatory regime over the last 12 months.

The BIA considers that the regulatory regime as it currently stands is satisfactory. However, we believe that, in some areas, specific guidance for biotechnology companies would help. The development of an industry Code of Practice by the BIA attempts to clarify certain "grey areas" for the benefit of industry and the financial community alike. We are unable to be more specific about particular code elements at this moment because of sensitivities associated with the ongoing development of the Code and the consultation process.

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[Continued

4. *Is there a conflict, real or perceived, between the requirements of the Stock Exchange for disclosure and those of the various medicines control agencies against promotional activities? If so, how could this be resolved? What controls are in place to monitor the accuracy of company statements regarding progress on drug or diagnostic developments? Are they effective?*

The BIA does not believe that there is any real or perceived conflict between the requirements of the Stock Exchange for disclosure and those of the various medicines control agencies against promotional activities.

In general, emerging biotechnology companies focus upon the same or similar areas of research and development as the much larger multinational companies which operate in pharmaceuticals and other bioindustries. The scientific and technical risks involved in such programmes are the same for both large and small organisations. However, the stock market value and momentum of the much larger established businesses are maintained by cash flows from marketed products and/or services. In contrast, in the SME biotechnology sector, most companies have few assets other than their intellectual property and the cash raised from investors at the outset, and have no products to sell.

The share prices of such emerging companies are very volatile and dependent on the stock market's perception of progress on their projects. They are therefore under great pressure to supply timely reports to the financial community on the progress of their research and development and this information is likely to have a significantly greater effect on the share price of small companies than it would for a larger business with a broader spread of products which are generating revenues.

Therefore it is the "materiality"—or the importance in context—of information which often poses problems. Through the development of an industry code, the BIA hopes that it will be able to provide specific interpretation of existing obligations to ensure better communication of information to the financial community.

5. *Is there a need for greater, or better, communication between the industry and the City? What benefits would this deliver?*

The BIA does not believe that there is a need for greater, but rather for better, communication. Biotechnology R&D is not inherently a news flow business but has become one. Better communication by industry and a greater understanding by other stakeholders would benefit the sector. Clinical trials by their very nature are trials. Of 15 compounds entering Phase I trials, only one is likely to survive through to marketing approval. The lead time between discovery and successful commercialisation in biotechnology is typically seven to 10 years. That is, investment in biotechnology companies should be seen as a long-term investment and it is important that the City clearly understands, and that the bioscience companies communicate, this.

Industry clearly needs to improve the way it communicates. As the BIA is reviewing this subject in the development of its Code of Practice, we feel that it would be inappropriate for us to comment further at this time.

The benefits of better communication would be more informed investors with consequently greater understanding of, and confidence in, the bioindustry.

6. *What progress has been made on the development of a Code of Practice for the industry? What is the intended impact of the Code of Practice?*

In December 1998, the BIA announced that it was developing a Code of Practice. Much painstaking progress has been made since then and we are still on target to publish a consultation document by the end of the first half of 1999, as previously announced.

The process is a complex one and we have involved the expertise of legal and accounting experts. We have placed much emphasis on doing everything we can to ensure the code is appropriate rather than rush through something in haste. A preliminary consultation phase will start in May amongst a representative sample of BIA members (via focus groups) and selected external experts. Feedback from this phase will be incorporated into the definitive consultation document which will then be circulated widely for comment (end June or beginning of July expected). We anticipate that the consultation period will run from July to September. Agreed amendments will then be made to the document as necessary and we plan to submit adoption of the Code to a vote at the BIA's Annual General Meeting in October.

When the definitive consultation Code document has been produced, we would welcome the opportunity to brief the Science and Technology Committee as part of the consultation process.

We believe that the Code of Practice provides the bioindustry with an opportunity to improve trust and understanding between bioscience companies and the financial community. We hope that the Code will become part of a wider programme of initiatives designed to ensure that all companies are fully aware of their duties.

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7. *What proportion of biotechnology companies use the services of an external scientific board? What are the advantages and disadvantages of using such a mechanism?*

As the BIA is reviewing access to appropriate scientific expertise during the drafting of its Code of Practice, we feel that it would be inappropriate for us to comment further at this time.

8. *The Committee would welcome the comments of the BioIndustry Association on the recommendations contained in its report on British Biotech and on the Government's response thereto.*

In preparing an industry Code of Practice we have reviewed both the Committee's recommendations and the subsequent Government response. We are unable to respond directly to this question at this moment due to sensitivities associated with the ongoing development of the Code and the consultation process.

We appreciate the Science and Technology Committee's continued interest in the biotechnology sector and would welcome the opportunity to brief the Committee at a later stage when the definitive consultation document has been produced.

9. Annex A, an outline of the regulatory regime applicable to biotechnology companies, is attached.

ANNEX A

1.1 INTRODUCTION

This summarises briefly the key features of the regulatory regime within which the industry operates. The BIA intends to include a chapter on guidance on legal and regulatory obligations in the Code of Practice. In particular, this guidance will be concerned with:

- (a) legal and regulatory obligations regarding the disclosure of information relating to companies' research and development, the progress of regulatory product approval and other investor information most of which is of relevance only to companies with listed shares or other securities; and
- (b) legislation and guidance (regarding the disclosure of such information) which is specific to biotechnology companies whether or not they have listed securities.

1.2. GENERAL

- (a) All Companies operate under a broad range of laws, regulations and non-legally binding codes in the United Kingdom which are relevant to the release of information to investors once their shares or other securities are admitted to listing on the London Stock Exchange (LSE) or quoted on the LSE's Alternative Investment Market (AIM) or EASDAQ;
- (b) These laws, regulations and codes are principally set out in:
 - The Listing Rules made by the LSE as the United Kingdom's "competent authority" in relation to the admission of securities to the Official List (the Listing Rules);
 - The rules of the LSE relevant to the admission of securities to AIM (AIM Rules);
 - The Financial Services Act 1986 and regulations made pursuant to it (FSA). This Act is to be substantially amended pursuant to the Financial Services and Markets Bill, and a draft code of market conduct to be made by the Financial Services Authority;
 - Common Law, principally case law, dealing with such matters as negligence and misrepresentation.
- (c) This document is intended to provide guidance on the obligations of companies once shares are listed or quoted on the LSE, AIM or EASDAQ. It does not deal with the obligations of disclosure operative at the time-shares or other securities are admitted to listing or quotation. In those circumstances, companies and their directors will obtain advice and guidance on their obligations from their sponsor (in the case of admission to the Official List) or nominated adviser (in the case of admission to AIM), and from their solicitors.

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[Continued

2.1 SECTOR SPECIFIC

Companies are also subject to legislation and guidance which is sector specific:

2.2 PHARMACEUTICAL SECTOR

Human Medicinal products

Legislation:

- The Advertising Directive 92/28/EEC;
- The Medicines Act 1968 S92-96;
- The Medicines (Advertising) Regulations 1994 No. 1932 and 1933.

(Note: UK legislation is interpreted in line with the governing European Directive).

Industry Codes:

- The Code of Practice for the Pharmaceutical Industry 1998 (Association of British Pharmaceutical Industry: ABPI);
- The PAGB Consumer Code 1998;
- EFPIA¹ Code;
- IFPMA² Code of Pharmaceutical Manufacturing Practices.

2.3 OTHER

Veterinary Medicinal Products

Legislation:

- The Medicines Act 1968.

Industry Codes:

- National Office of Animal Health List.

Examination of Witnesses

MR ROBERT MANSFIELD, Chief Executive of Vanguard Medica Group plc, DR JOHN SIME, Chief Executive, the BioIndustry Association, and DR PAUL HAYCOCK, Director of Biotechnology Division, Apax Partners & Co Capital Limited, the BioIndustry Association, were examined.

Chairman

1. Mr Mansfield, may I welcome you and your colleagues to our Select Committee which is sitting quite unusually in the middle of the parliamentary recess. Because there is a lot of maintenance work going on, as you will have seen outside, things are disrupted, cupboards are locked and we have not got keys. We have not got our name plates, although we have been able to make some for you. So we know who you are but it is not so easy for you to know who we are. Can I just introduce people around the table. On my right, your left, is Dr Lynne Jones. On my immediate right, Mr Nigel Beard. Myself, my name is Michael Clark. On my extreme left is Dr Ian Gibson. If you do choose to call us by name those are our names but if you cannot remember them, if you look at us we will assume you are talking to us and we will respond accordingly. I am going to ask you a question in a moment or two but just before I do so, would you care to introduce your colleagues to us, or let them introduce themselves. Can I say, Mr Mansfield, we will address our questions in the first instance to you but if you think it is more appropriate that they should be fielded to one of your two

colleagues, that is your decision and perhaps you would like to do it, or they may indicate that they wish to come in, in which case we shall invite them to speak.

(*Mr Mansfield*) We are very pleased to be here this morning and to have the opportunity to interact. I am Robert Mansfield, the current Chairman of the Bioindustry Association which represents companies in the bioindustry here in the United Kingdom. I am also Chief Executive of Vanguard Medica which is a publicly quoted company, has been on the London Stock Exchange for about three years and was formed around venture capital, so has had some personal experience of being a very young company starting up in the UK and coming through to the market with the responsibilities and obligations of communication of information to the public. Dr Paul Haycock.

(*Dr Haycock*) Good morning. I am a current Director of the BIA and have been for a number of years. I was previously Chief Executive of Cantab Pharmaceuticals, one of the first biotech companies in the UK, and listed on NAZDAQ in the early days and then on the London Stock Exchange. Prior to that I was Chief Executive of various pharmaceutical

¹ European Federation of Pharmaceutical Industry Associations.

² International Federation of Pharmaceutical Manufacturers Association.

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MR ROBERT MANSFIELD, DR JOHN SIME
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[Continued]

[Chairman Cont]

companies. Currently I am a partner with Apax Partners who are a venture capital house very involved in investing in this sector in the UK.

(*Dr Sime*) John Sime, Chief Executive of the Bioindustry Association.

2. Thank you very much indeed. Mr Mansfield, why did your organisation think it necessary to develop a Code of Practice covering the management of information for the biotechnology sector?

(*Mr Mansfield*) That is a very important question, Chairman. We had been thinking about trying to introduce some guidelines over the last couple of years but frankly the events of 1997 and 1998 in the UK, and some similar events in the past in the United States, encouraged us to grasp this nettle and to try to introduce some guidelines for our member companies. I think, in fact, we were strongly encouraged by the interests that Parliament, through the Select Committee, took in these matters as well. We know that the Government here in the UK considers biotechnology to be a very important sector for the UK going forward and we felt that it was very important to establish a better level of trust and understanding between the communities as a whole but particularly the investment community and the companies. We thought it appropriate to step in and to put together a Code of Best Practice after extensive consultation around the City and with interested parties.

3. Thank you very much indeed. We are pleased to think that our investigations, and particularly our report into British Biotech, might have had an encouraging influence upon you. We were conscious at that time of the absence of such a Code and we are delighted that it was either already in the pipeline in your organisation or that you responded so very quickly following that company's experience and similar things that were happening at the time. Can you tell us whether the Code is entirely new or does it supplement existing codes, such as the Code that is already in place from the ABPI?

(*Mr Mansfield*) Yes. We studied the ABPI Code of Practice extensively and of course we also looked at all the advertising standards and the current documentation and recommendations from the London Stock Exchange. We came to the early conclusion that there were already very substantial regulations in place. The real question was whether people were aware of them all, whether they understood them all, and whether they had been suitably interpreted for these young companies that are emerging very rapidly from an early science and technology platform through to being publicly quoted companies with all of those responsibilities. What we found was that the substance of many of the things which are currently included in the Code were in fact already there but needed to be elucidated and expanded and exemplified for these young high technology companies. It was quite interesting in talking to major institutions and advisers in the City that the conclusion they drew was that many of the things that are included in here are probably not just appropriate for biotechnology companies but also appropriate for many forms of high technology company where based upon investment over a period

of two to five or ten years investors are putting faith in management and in projects for which there are yet no sales or no measurable performance.

4. I would assume, unless you tell me to the contrary, that ABPI have been supportive and would see this as complementary to what they want to do and no rivalry would exist?

(*Mr Mansfield*) Absolutely. Dr Sime and myself have been in contact with Dr Trevor Jones who is the current Chief Executive of the ABPI. He has given us substantial feedback. We found on examination of the ABPI Code that an awful lot of it was directed, in fact, to complaints or competitive scenarios between companies who were marketing existing products. As you probably are aware the quarterly documentation published by their sub-committee explains all the complaints and the peer review of those complaints. We found, in fact, that the content of the Code of Best Practice was frankly more to do with good corporate governance and investor relations than to do with competition between companies in the advertising.

5. A final question from me before we go to Mr Beard. Do you see this Code of Practice as the final piece in the jigsaw of regulation and controls on the biotechnology sector, or do you think there will be other methods? If you do think that this is the final piece in the jigsaw, how often do you think it should be revised?

(*Mr Mansfield*) That is a very important question, Chairman. We think that this is part of the whole question and debate around biotechnology at the moment but obviously a very important one because investor confidence has been severely undermined over the last couple of years. Some of the people from the press and others that we have spoken to have said: "there are many other areas of biotechnology that you might have included in here", but we feel this is really a stand alone document to do with how companies should behave and communicate. We also believe that with the benefit of experience over the next couple of years, we are sure that the wording in here and the principles will evolve and maybe some additional principles will be added. I hope it has come through to the Select Committee that we intend to appoint a totally independent, probably a barrister as chairman of a sub-committee who will in fact be looking at this Code of Best Practice over the next couple of years and chairing our sub-committee on that Code and we would not want to limit the freedom of that chairman to make refinements to the Code as and when he sees fit.

Mr Beard

6. How does the Code as it stands at present compare with regulations in America and the European Union?

(*Mr Mansfield*) That is a little difficult for me to answer, but I will tell you the extent of our knowledge so far. We did consult with the ABI, the Association of British Insurers, who told us that they were aware of about 60 or 70 codes from industry associations around Europe and I remember we asked whether they were aware of anything that could be used by us to compare and they thought that frequently it was to

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[Continued

[Mr Beard Cont]

do with more industrial things rather than corporate governance, so we are not aware that anything like this exists in European countries. Frankly, in the United States it appears that companies rely very heavily upon SEC regulations and also advice from their lawyers as to what to do and you may be aware that young and older companies in the United States are frequently the recipient of legal actions by shareholders if anybody feels that any information has been inappropriately communicated or has been misleading.

7. So there is really no equivalent to this?

(Mr Mansfield) No, we are not aware. In fact through the BIA, we put the document on to the Internet and people have been able to read it from all around the world and we have had some interesting comments back from, I believe, Australia and also from Canada, similar groups over there who found it very useful and may well use it as the basis of something in their own countries. I have not had any direct comments from the US, but possibly Dr Sime may be able to add something.

(Dr Sime) The Bio Organisation, which is our sister organisation based in Washington, has no such code, so it is unique. We have discussed it with them and they know what we are doing and they are supportive of it, but they do not have an equivalent.

8. The position in Britain when this Code comes into practice, into effect, will be that listed companies will be regulated both by this Code and by the Stock Exchange Code and non-listed companies will be only regulated by this Code. That is the case, is it not? Is there a big distinction then between the non-listed companies and the listed companies?

(Mr Mansfield) I would like to pass this over to Dr Haycock.

(Dr Haycock) One important distinction to make is that the use of the word "regulated" by the Code is not quite correct and is not quite what is meant.

9. Effective?

(Dr Haycock) We are trying to lay down a Code of Best Practice, but it is not a legal or regulatory framework, so I would like to be clear on that. As to the difference between the public and the private companies, in one sense I believe there should be very little difference in the way that they conduct their affairs and their responsibilities to investors, who albeit are private investors, just in the same way that they have responsibility to the public shareholders once a company is listed. In practice, the public companies tend to be of course more visible and there is more transparency, or there should be more transparency in what they are doing because of the nature of the public listing, but the principles in this Code should apply equally to public and private companies and there is really no distinction.

10. I understand that, but the real gist of the question was whether the extra prescription of the Stock Exchange Code on listed companies brought something into effect for them that was not applied to the non-listed companies.

(Dr Haycock) Absolutely, yes. Once one is listed, you are subject to the Stock Exchange's Code, if you like, and their regulations which private companies are not. However, the point I was trying to make was that I do not think there is any contradiction between our Code of Best Practice and what indeed is laid down in the Stock Exchange.

11. I understand there is no contradiction, but is there any part of activity that is not covered by your Code for the non-listed companies that is covered by the Stock Exchange Code for the listed companies?

(Dr Haycock) As far as I am aware, there would not be any area of significance which is not covered by ours, no.

Chairman

12. Could I just interject for one second. Dr Haycock did say that this is not regulation, that this is a Code of Best Practice and that we understand, but I declare that Dr Sime and I did have a private conversation soon after this Code had been produced and I understood from that conversation that, although it was a Code of Best Practice and not regulation, members of your organisation failing significantly to meet this Code of Best Practice could risk being asked to leave your organisation and would be sanctioned in that way. Is that correct, Mr Mansfield?

(Mr Mansfield) Yes, Chairman, it is, and all the feedback that we have from the investment community and the professional advisers, the banks, the accountants and the lawyers who have been very heavily involved in this, and all the major banks and accounting firms have been helpful to us, their advice is that what was required was a clear statement of what best practice should be and we found that the most subtle but effective way to ensure that companies were making a public statement on this was to require a statement in the annual directors' report. Now, within the public and private companies there will be an audit committee and the head of the audit committee will be a non-executive director and we believe, post the introduction of this Code, that there will be some extensive reviews within both private and public companies to ensure that the companies are complying with the Code of Best Practice. Now, we also believe that institutional investors and private venture capital investors who fail to observe a statement in the directors' reports saying that they are in compliance will be asking those companies why and we suspect that this may well become a requirement for investment in those companies going forward. I would like to point out that there is not a huge difference between who invests in private companies and public companies because most of the venture capital funds in fact are funded by institutions from the City, insurance companies and so on, and the intention with many of those companies is to access the public markets later on, so anything that they are doing in the private, early stage which is in direct contradiction of what would be required later on is obviously misdirected.

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MR ROBERT MANSFIELD, DR JOHN SIME
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[Continued]

Mr Beard

13. Are each of the principles in the draft Code of equal weight and, if not, which are the more important ones?

(*Mr Mansfield*) That is a very good question, but a very difficult one to answer. I think what we tried to address, Mr Beard, was the range of issues that had been identified over the last couple of years. Now, I guess every company and every situation is different and the other thing is that in each of these companies there are dynamic situations. A young company may be moving from science and technology into early-stage development and then later-stage development with interaction with the regulatory authorities and the stock markets and so on, so frankly the major issues within an individual company will change over time and from year to year and it is, therefore, very difficult to say that any one of these principles is more important than another, but we do believe that these nine principles, as far as we can see, address the major issues which have occurred in the last couple of years.

14. Why have you felt it necessary to divide this into effectively two layers, one being the principles and the other the provisions? Does that not run the risk of some ambiguity between the two?

(*Mr Mansfield*) I hope not, Mr Beard. It was quite deliberate and, as you know, we took very extensive advice along the way from Cameron McKenna who provided two partners in the process and worked very closely with us. One of those was intimately involved as a partner in regulatory affairs and the other was intimately involved in corporate affairs and companies' interaction with the Stock Exchange and the public markets, so we had very good legal advice there. Now, what we wanted to avoid was a box-ticking exercise where any company could look at a long list of rules, tick the box and say: "We have complied". We, therefore, thought it was very important to define the principles and to leave it to the boards of directors of the companies to consider those principles and where and how they applied to the issues that the companies were facing. However, principles on their own, without a discussion or an explanation of what those could mean, we thought would be rather too bald. In this first attempt at the Code of Best Practice under the provisions we have exemplified and illustrated the sorts of things that a Board would need to consider. That is obviously not an exhaustive list and I suspect that will change over the next couple of years or will be added to.

15. It is there for illustrative purposes?

(*Mr Mansfield*) Yes.

16. What do you mean when you say that the Code is "supported by the more detailed provisions"? Is that the nature of what it means, that they are illustrative? The Code says that the principles are "supported by the more detailed provisions".

(*Mr Mansfield*) My personal view on that, and I am not a lawyer, is that we are really trying to illustrate there in order to guide people as to what is meant in the principles and the sorts of situations that might arise which they should address.

17. The wording also goes on to say that the companies "should" observe the principles but it says only that they "may" apply the provisions.

(*Mr Mansfield*) Could you please direct us to a particular page?

18. It is page ten, paragraph 1.4, line six: "There are also more detailed provisions and it is for those BIA members to apply these provisions in ways which best suit their particular circumstances and report to shareholders."

(*Mr Mansfield*) I think, Chairman, the attempt here, at least in the English, is to explain that the principles should be applied broadly across all companies. In our review of the range of different companies and the range of different stages of development of those companies we concluded that the provisions would not apply to each and every company because they may not be facing those issues, albeit at that stage.

Chairman

19. So the provisions are a little bit by way of an example.

(*Mr Mansfield*) Yes.

20. Which would apply to many but not necessarily rigidly to every single one?

(*Mr Mansfield*) Not necessarily to every single one.

Mr Beard

21. But you would expect your members to apply the provisions where they evidently relate to their current stage of business?

(*Mr Mansfield*) I agree.

Chairman

22. Or similar ones?

(*Mr Mansfield*) Yes. There is no freedom or flexibility there. It is: "if applicable then apply it".

(*Dr Sime*) I think the distinction is that the principles are what we are trying to achieve and the provisions are an example of how we are trying to achieve it. It is not intended to be prescriptive and it is left to the Boards of Directors of those companies to choose the method themselves of achieving what we want the principles to achieve. The provisions are up to the Boards of Directors.

Mr Beard

23. Do you think it would be helpful in the next one just to clarify that point?

(*Dr Sime*) Yes.

24. Because I do not think it is clear from the way that it is drafted at the moment. Later on there is an implication of "must" rather than "may" in the way that the provisions are spoken of. I accept that the principles are all there as fixed principles that should be obeyed but then the elaboration is through the provisions and some people would not expect to take them up and others would. I think you may need to say that you expect people to take them up where they apply at their stage of development and they only have an obligation to leave them behind because of their irrelevance, not because of choice.

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[Mr Beard Cont]

(Mr Mansfield) Yes. I think that is a very good suggestion.

Chairman

25. Would you look into that further?

(Mr Mansfield) Yes, we can.

26. Would you care to drop us a note after you have done so?

(Mr Mansfield) We certainly will. We are just coming towards the end of the official period of consultation and in the next week or two we will make some final revisions to the wording and I think that is a very sensible suggestion.

Dr Gibson

27. I am concerned about the principles and provisions too, and Dr Sime has clearly defined those, because of our experience with British Biotech, and they were non-executive directors who were absolutely clueless really in preventing what happened on the Board. You have made some suggestions about the independence of non-executive directors but would you like to say something about that, how they should be different from other members of the Board, how you see them operating in the light of past experiences in the industry and how the Code will operate within that?

(Mr Mansfield) Yes. This is obviously a very complex area, Dr Gibson, and from the example you have raised there are some lessons to be learned. If I can just refer to Principle Three which talks about the supply of information to companies' Boards. Frankly, we feel that it is terribly important that all pertinent and relevant information is being reviewed with the Board regularly so that the executive and non-executive Board members are aware of the major issues and complexities that the company is facing. We also believe that it is almost impossible in a young company to staff it with a non-executive Board that will have the answers or the relevant experience for each and every one of those issues that will arise over a period of five to ten years in the development of a project. We have therefore called upon companies to make appropriate use of external scientific, clinical and other relevant expertise where appropriate. Frankly, I think the answer to the question is the sum of those three different measures: supply of good information to the Board; a good balance of relevant experience within the Board; and the use of external advisers. There are many companies within the Bioindustry Association that are already applying those principles. We think then that the independence of the non-executive directors will be less of an issue because the procedure will be if they as individuals do not know the answer or do not have the relevant expertise then automatically the company will go outside.

28. What is the role of the non-executive director going to be? I have never been one so I do not understand the function of them in this industry. What are they actually going to do if they are not independent, do not feel that they can challenge

decisions and come in there and take the executives on on an issue? As you describe it they seem to merge into each other.

(Mr Mansfield) Dr Gibson, I think that is probably a question for possibly the Institute of Directors or the CBI, the role of non-executive directors in any company. Recently, as we have seen with Cadbury and Greenbury and other attempts at corporate governance, there seems to be an increasing role of the non-executive director to really try to protect the interests of the external shareholders, which is a very, very important role. I believe that the best non-execs within our sector are doing just that. The question is in order to do that on technical and scientific issues they have to have the relevant experience. If we look back at Principle One in our Code we are saying a balance among non-executive directors between those who are experienced in business development and those who are familiar with the risks and uncertainties inherent in the biotechnology sector.

29. That has got nothing to do with science, has it? That is about business acumen, it is not about the scientific understanding of the nature of the problems of clinical trials, the assessment of them.

(Dr Sime) It is intended to include those.

(Mr Mansfield) It is our intention, Dr Gibson. If I could just broadly state that there is research and development and frankly most of the issues in which companies in this sector have experience and which have gone recently have been to do with development.

(Dr Haycock) I sit on a lot of Boards in the UK and in the US, most of them young early stage biotechnology companies, and I find that the non-executives when the thing is working properly can bring a terrific amount to the body. They are there essentially to protect the shareholders and investors' interests and be a truly independent arbiter of the way that the executive is managing the company. Generally speaking the mix on most Boards is between science and business experience but often the same people have originally been scientists and then gone on to run companies of their own, be involved in big pharma companies and so on. There is a wealth of such experience available on both sides of the Atlantic. I think the role of the non-executive is clearly defined and the mix of experience and scientific knowledge base is there and when applied properly can really help with the running of the company and that is what we are trying to encourage.

Mr Beard

30. Could I exemplify the anxiety with reference to British Biotech, where the company started off with a balance of the sort you are describing between the business and the scientific interest and as essentially the row developed in the company and people fell off the horse, it became quite a different balance of expertise within the company. Who is going to monitor this process and this balance as it evolves because it is not just a fixed thing? There are not fixed positions for people, but people can be appointed and reappointed, as they were with British Biotech and you ended up with a board which had very little scientific and development experience on it.

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(*Mr Mansfield*) Mr Beard, good practice is to have a nominations committee within a public company and there are frequently nominations committees in private companies too. I think with this Code of Best Practice as a guide to achieving the right balance between commercial and practical pharmaceutical industry and industrial experience and clinical expertise too, then we feel that the nominations committees and the chairmen of these boards will have the right sort of guidance for these companies. However, frankly I have to refer to the broader picture which is the whole role of non-executive directors, as Dr Gibson has raised, and I think this is particularly relevant in young companies where frequently the company is to a larger extent than with major companies relying on a level of expertise and experience from the non-executive directors to help to guide them in their formative years.

31. Would you consider it part of your role as an association to monitor this and if you saw a company which was moving to an imbalance between business and scientific backgrounds in the company to say: "Well, you really are moving out of the provisions of this Code"?

(*Mr Mansfield*) That is a difficult one to answer, Mr Beard. I think the role of the BIA is to establish what best practice should be rather than necessarily to police it, but we feel that shareholders who of course have the right to vote on the appointment or reappointment of executive and non-executive directors on a regular basis under the Companies Act will be taking this more seriously in the future because, as Dr Gibson pointed out, there have at least been some serious questions as to whether the right balance has always been there on public company boards in the past with the relevant experience and whether the right flow of information is coming through to them. You cannot take any of those in isolation and I think everything has to be working for the board to be effective.

Dr Gibson

32. You raised the question of external advisers and I am quite interested in that too because I think it is a difficult area to get the right advice. How do you foresee confidentiality as being part of the appointment process of those individuals and is there a situation where a company might not want to imply that confidentiality was part of the external advice? How do you handle it? Are they just going to be tame running dogs of the biotech industry or are they going to be real people who assess data in a scientific and technological way and really they feel independent; and where does that independence relate to the profits of a burgeoning industry which is very competitive, for example? How do you hire them? Where do you find them? I do not know of any, so tell me.

(*Mr Mansfield*) Well, I can give some comments here from my own company's experience of the last eight years and I suspect Dr Haycock can too. Just briefly, the sort of issues where one needs really world-class counsel are on patents, intellectual property obviously, the interpretation of toxicology data on medicines in the early stages and then the design and review of clinical trials, clinical trial

information in phases one, two and subsequently in phase three. Now, for that sort of information, you really do need top-level expertise, otherwise it is hardly worth taking the advice and the experience in my own company is that one normally signs a confidentiality agreement, and in fact in every case one does, and the reputation of the people that operate as consultants, obviously if they break confidentiality, then their reputation will be ruined. I personally have never had any bad experiences in that respect over the last eight years dealing with consultants in the United States, Europe and here in the UK and frankly it has worked very effectively, but I think it is also up to the board, and especially considering the provisions we have put into the Code here, to make sure that the right people are chosen to give advice and that the advice is considered very carefully when it is received.

33. So what would happen in a situation, for example, where somebody gave you the advice after their assessment of clinical four-stage trials and said: "No way should this be marketed", and then you went and marketed the product after all the discussions and then they went to the press and said: "This is absolutely inhumane, unethical, unjustifiable"? They would either get a CBE, a knighthood or they would be destroyed in their reputation, as you said, but which would it be, do you think?

(*Mr Mansfield*) Dr Gibson, in that particular example, which is a late stage, there is in fact an incredibly tough system in place to avoid that happening. The requirement for any new medicines to come through to the marketplace means that you have to submit it in the United States to the Food and Drug Administration and here in Europe to the various local country or European regulatory agencies. The period of review is generally about a year, maybe a year and a half and every detail associated with a potential new medicine is assessed, including visits to the places where they are manufactured and audits on the centres where clinical trials have been carried out. It is a very extensive and time-consuming process and that is not the only check. In fact in order to perform clinical trials, companies have to apply for permission, submitting data supporting the application, before clinical trials can even commence, so I think my personal view on that is that it is very unlikely that a company could override the counsel of external advisers and get a product to the marketplace because the existing regulatory system which has been in place for many years would mean that an extremely thorough review would take place.

34. So you do not think that there needs to be a reassessment of the whole clinical trial assessment process? In this country there have been media reports and consultants have looked at them and said: "The British system is pretty lousy on it", so do you not think that needs to be looked at seriously from your organisation's point of view?

(*Mr Mansfield*) Dr Gibson, I must admit I have not heard that comment myself. I think my personal view on the Food and Drug Administration and the European agencies is that they are doing a very thorough job. Sometimes I think there are requests that the system should be more transparent or

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[Dr Gibson Cont]

possibly operate more rapidly, but I have never heard anybody say that they think they are not doing a thorough job. I think that the point relating to these young companies is more to do with communication by the young company of their view on the status and progress on individual projects and medicines as they are coming through, but I would like to hand over to Dr Haycock if I could, Chairman, for some additional comments.

(Dr Haycock) I would just endorse that. I think the regulatory system in Europe and the US for the approval of drugs for market is actually very tight indeed and is a very good system. What we have here is the problem of the communication by a young company of expectations of a clinical trial, saying: "This is going to be wonderful. This is going to be positive. This will all be done by March", and then it is not wonderful and it is not done by March or whatever. That is the area that we are trying to address here, which is the reality of communication in a responsible fashion of expectations of clinical trials and of course if there is a balancing act, young companies want to put out good news and a good feel and keep investors interested and so on and of course clinical trials are risky things and they do not always succeed and drugs do not succeed, so it is that aspect that we are concerned about. The actual approval of drugs for sale is well regulated in this country.

(Mr Mansfield) If I may just make a point here which I think is important for today's considerations, in setting up best practice, unfortunately we cannot set up any guidelines which will avoid the failure of individual compounds or projects in high-technology companies and I think sometimes the external reaction when a company does have a disappointing result is confusion between whether management have done the right thing and communicated appropriately: "Did we expect this to be a runaway success?", and "How disappointed are we in the failure?", and unfortunately the experience over many decades of the pharmaceutical industry is that products or compounds do fail and continue to do so in very large organisations too.

Chairman

35. Mr Mansfield, I have not worked in the pharmaceutical industry but I have worked for a considerable number of years in the chemical industry and my experience is that successes do not need much managing, they manage themselves, the euphoria manages itself, it is the failures and disappointments that need managing. I take it that the principles you have laid down as much as anything else are to guide people on how to manage the disappointments rather than how to manage the successes?

(Mr Mansfield) Yes, I completely agree.

Chairman: Can I just say that we were hoping to finish at 10.30 but clearly we are not going to. I will allow an overrun of ten minutes to 10.40 but at 10.40 we must finish. I say both to the Committee and the witnesses if you can help us to finish by 10.40, otherwise it means one or two questions will be left pending and they will have to be answered in writing which is never quite as satisfactory as dialogue.

Mr Beard

36. Principle Five at the end refers to an expression of opinion on the factual information that a company is putting out on the progress of its research and development. Is it appropriate that opinion should figure at all in that dissemination of information? Is it not likely that if opinions are put out they are going to be looked on by the world at large as facts? Would it not be better to keep the information purely factual?

(Mr Mansfield) I think that is a very good question, Mr Beard. I think the most important application of this principle is to do with the size of markets which a drug may be addressing and the potential sales that a drug may achieve and the competitive profile of that drug compared to existing products in the marketplace or to other emerging compounds of potentially new medicines that are coming through. Frankly in an ideal world, in a pure world, one would not be required to make any comments about these situations but in the investment community they are very interested to know what a company thinks and they will in fact write extensive research from the analysts in order to try to address this because it then determines how interesting the project is and what level of investment they think should be made in the company. So it is very difficult to avoid that. I think here in this principle we are saying that if a company is making market forecasts or beginning to address those sorts of questions then it should be very clear to the lay person and the lay investor that these are company estimates and opinions rather than facts.

37. Do you think it would be useful to put an example of what you think is admissible opinion and what is not in the provisions?

(Mr Mansfield) I think that is a very good point and we will consider that next week.

Dr Jones

38. Principle Seven relates to the disclosure of price sensitive information. The announcement of collaborations between early stage bioscience companies and an established company can have a significant effect on price, as you have implied in the explanatory notes. Therefore, would there be merit in giving explicit recognition to this within the principle?

(Mr Mansfield) I am sorry, I missed the last part of your question.

39. It is having explicit recognition in the principle of disclosure of collaborations with larger established companies. It is back to this business about principles and provisions.

(Dr Haycock) This is an area where there is actually not too much problem usually in getting disclosure in the sense that companies are usually delighted to be making a positive announcement of a collaboration of any sort with a major pharma company or anyone else because it gives endorsement to their technology. To the best of my knowledge this is an area where people are really very keen to disclose what is happening. Where they are not so keen, of course, is when that collaboration is terminated for various reasons which could have a negative effect. I think if we are going to put in

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[Dr Jones Cont]

specific examples we need to look at both ends of that particular equation. Having been on both ends myself I know the difference.

40. It is a question also of actually when an announcement is made and there may be discussions going on.

(*Dr Haycock*) Speculation about collaboration, if that is what you are referring to, is a rather different matter and until the deal is signed it is not done and rumours about a deal that is about to be done generally speaking are not helpful and are, in fact, harmful to a company. A press release on the signing of a collaboration is a clear event. Any speculation prior to that is generally speaking not helpful to that company or the industry. It is that sort of example we could perhaps refer to.

Dr Jones: The point is about making it explicit in the principle, that this is an important issue and there needs to be some explanation about how that should be managed.

Chairman

41. Could you just look at that as well? One or two things have come up and we are trying to be constructive. We are approving in general of the guidelines you have set down but it would be surprising if we did not have one or two ideas and, as we put them to you, could you just indicate that you will look at them and perhaps, in that note you are going to give us in due course, include this one too.

(*Mr Mansfield*) Yes. Chairman, I think the suggestions so far have been very constructive and very helpful. The point that Dr Jones was just addressing is a very important one. I am sure if any of us open up the FT or any of the leading newspapers on a daily basis there will be speculation about what companies will do. There is frankly extensive press and analyst speculation about what these young companies will do which is often a little awkward for the companies to deal with because if they completely refute it it could affect their share price and if they begin to wink and suggest that may well happen then they are encouraging further speculation. It is very difficult. We will try to expand on that.

Dr Jones

42. There is also the question about who actually makes important announcements. I wonder whether it should be in the Code that these should be made jointly by the partners rather than severally as is the case at present?

(*Mr Mansfield*) I think that is a very good suggestion but in some cases large companies or privately held large companies do not actually want to have a joint statement at the time of the press release. In my experience, and I suspect Dr Haycock and Dr Sime would have had similar experiences, we have never been able to issue a press statement under a contract on any form of deal with another partner which did not have their sign off of the press statement prior to it being given out.

(*Dr Haycock*) I agree. Generally speaking it is done as a joint release but certainly both parties would have seen the other's release that is going out. Some

of the larger private companies or public companies may have a policy that they do not do that, a huge corporation will not do that.

43. If it was explicitly laid down it may help to rest some of the speculation when perhaps one partner is under pressure to make announcements. It may actually help support them in resisting that kind of pressure.

(*Mr Mansfield*) Just very briefly, if I could. Normal practice within our sector, because these statements are so important, is that frequently the sponsoring bank, ie the investment or merchant bank, the lawyers and the company stock brokers will be involved in the review of those press statements before they go out. There is normally an extensive consultation before the press releases are issued.

Mr Beard

44. Principle Eight applies to the development stage where a product is being regulated but it does not give any particular milestones at which a company should comment on the progress of regulation. There are milestones in the progress of the regulatory approval for pharmaceuticals and I believe there are probably milestones in some other areas. Would it not be a good thing to advise companies quite specifically that they are under an obligation to publish something at those stages rather than leaving it open to them to publish good news when it arrives and neglect the stage when it is bad news?

(*Mr Mansfield*) That is a very complex area, Mr Beard. If I could just very briefly summarise. In the development of a pharmaceutical product, which generally will take somewhere around five to possibly six years, companies normally are very clear about when they commence phase one studies, which is the very first phase. Frequently they will publish some sort of statement or possibly even information when they have completed phase one moving on into phase two. They will have to submit data to the regulatory agencies in order to continue on into phase two and then they will have what is called an end-of-phase-two review with the regulatory agencies in the United States and possibly Europe if they are doing studies in Europe in order to continue on into phase three. In most cases, if not all the cases that I have seen in the past, companies are pretty clear about what is happening and at what stage they are. Now, the major issue arises later on which is that when all this data has been put together and submitted to the regulatory agency as a United States' NDA, a new drug application, it will be a huge dossier, a massive dossier, requiring trucks to take it down to the Food and Drug Administration, and similarly here in Europe. At that stage you go into a period of a year or possibly 15 to 18 months of very extensive review and discussion and requests for further analysis and possibly further information. Now, I think the view of the industry association, because we did debate this at great length, is that during that period, that year or so, it is not considered to be best practice for

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companies to begin to stimulate expectation that they will necessarily be successful. On the other hand, we do not think it is best practice that a press announcement to the London Stock Exchange is made every time a question arrives from the regulatory agency; that would be impractical frankly. Major pharmaceutical companies face exactly the same problem and sometimes things go wrong and things are delayed for a year or two and then press statements are made, but during that period of a year or 15 months, we believe that probably best practice is for companies to remain pretty quiet unless there is something very significant to be published.

Mr Beard: I understand that and I entirely agree with what you are saying, so that the thing is not talked up in the process when there is no evidence, but at the end you mentioned the pharmaceuticals and there are different milestones of the different phases and presumably there are in other aspects of the biotech regulation too. My question is only: should there not be a presumption that the company will report at the end of a relevant phase on what has come out of it rather than leaving the possibility that a company gets to the end of a relevant phase, the news is not too hot and it does not put anything out, but that when the news is reasonable, it puts it out? Should it not be a requirement on the company actually to publish something at the relevant milestone, not speculating between, and I entirely accept that?

Chairman

45. Please be brief, Mr Mansfield. "Yes" is about as brief as you can get.

(Dr Haycock) The simple answer to this is that yes, there is a reasonable expectation that information should be put out at those milestones, at the end of phase two or whatever, and, by and large, it is because even if the news is not so hot, as you put it, generally speaking, investors and analysts demand that those data are made available.

Mr Beard

46. Would it not be wise to put that as a provision in the Code?

(Dr Haycock) I think we could very well consider putting it into the provisions section with the appropriate wording.

Dr Gibson

47. With everything in your Code, how would it have prevented the events of British Biotech and Cortecs happening? Finally, what are you going to do about the companies that are not in your organisation and not on the list? How are you going to see that they are disciplined? How are you going to get them to become members?

(Mr Mansfield) Dr Gibson, those are two very important questions. As to the first one, I must be very frank on this. I think we collectively need to look forward and I think many of the things that are included in the Code here frankly are drawn from the experiences of the last two years and had this

framework been in place, had the boards been operating on this basis, had the shareholders been reviewing the performance of the company and looking for compliance and best practice in directors' reports, then it is possible that some of the sad events of 1998 may not have happened, but it is very difficult for us to give a black and white answer on that. Secondly, we believe that those companies that are not currently members of the Bioindustry Association may well be encouraged by their investors to join and even if they do not, as a requirement for continuing investment and support from the investment community, they may well be required to make a statement that they are complying with the Code and frankly they do not have to be members in order to apply this Code.

Dr Jones

48. On page 4 of the consultation document you actually say that the BIA is not a regulatory authority and it has neither the power nor the desire to monitor and investigate its members' conduct. You seem to be relying on disclosure by the companies in their annual reports, so who is then going to monitor compliance with the Code and alert the BIA to breaches?

(Dr Sime) We go back to the point that companies are expected to note in their directors' reports whether they are in compliance or not, so effectively anybody that reads that report is in a position to lodge a complaint if they do not believe it is correct, but almost anybody else could lodge a complaint based on their observation of what the company is doing.

49. So you are relying on whistle-blowers basically to inform you and you are not doing any kind of routine monitoring as an organisation?

(Dr Sime) I do not think there is very much monitoring in terms of investigation anyway that we can do. I think it is always going to have to be dependent upon people bringing things to our attention. I do not think we have either the power, the resources or really the mandate to go into companies and to demand information. We can ask people to come along to explain themselves on the basis of either our observation that things are not going well or someone pointing that out to us.

50. So what is the point of having the Code if nobody is actually checking it out other than relying on people perhaps to put themselves in a very difficult position in blowing the whistle?

(Dr Sime) I think the whole tenor of the evidence we have been giving this morning is that there is a community expectation, and we have had it explained to us or stated to us by representatives of investing organisations, that they will make continuing investment in those companies contingent upon those companies being seen to comply with this Code and those external teeth, if you will, are at least as important as anything that we can do inside. After all, the Greenbury Code and so on has no teeth at all and yet no one dares not abide by it.

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Chairman

51. Can I remind you that you did tell us earlier that you would expect your member companies to have a statement in their annual report that they are abiding by it and if, therefore, they are not abiding by it, having put that in their annual report, they are seen to be—

(Dr Sime) They would be in breach of the Code.

52. Well, they are seen to be charlatans of some sort by making a statement that they are not actually complying with. That would be a sanction, would it not?

(Dr Sime) Yes, it would.

53. Well, we have finished more or less in line with our second timetable. Mr Mansfield, I hope you have found this as useful as we have this morning. It is a follow-up session that we thought had some urgency and that is why we are sitting during what is a Parliamentary recess. We wish to issue a short report saying that we have followed up on our earlier recommendations that your industry, perhaps already minded to bring in these principles and provisions, was encouraged a little bit by our interest

in what you are doing and we think it has been a satisfactory conclusion. The final question from Dr Jones about sanctions and monitoring is really the acid test, but that can be either done through self-assessment or through whistle-blowing, but we would rather have self-assessment and we would rather have something much more up-front than whistle-blowing. We have left you with four or five questions that we hope you will respond to in due course after proper reflection, but, above all, may I thank you and your team for being here this morning and helping us with this inquiry and we wish you well in implementing this important step forward that you have now taken.

(Mr Mansfield) Thank you very much, Chairman, and thank you very much for your suggestions which we will certainly consider very carefully next week. My personal view is that the whole framework from the professional advisers, the bankers and the investing institutions, the pressure that they will bring on these companies will make this a very effective Code going forward.

Chairman: Dr Haycock, Dr Sime and Mr Mansfield, thank you very much indeed.

Memorandum submitted by the London Stock Exchange**1. INTRODUCTION**

1.1 The London Stock Exchange (the "Exchange") submits this memorandum in response to the questions raised by the House of Commons Science and Technology Committee (the "Committee") in its letter to Gavin Casey, the Chief Executive of the Exchange, dated 8 April 1999. This memorandum supplements the one submitted by the Exchange on 7 July 1998. For the convenience of the Committee, an explanation of the Exchange's functions, previously provided in our memorandum of 7 July 1998¹, is included as Appendix 1.

1.2 For ease of reference the various points on which you have sought comments from the Exchange have been addressed under separate headings below.

2. "What are the key features of the financial regulatory regime within which biotechnology companies listed on the Stock Exchange operate?"

2.1 The financial regulatory regime within which listed biotechnology companies operate is the same as that which governs all UK listed companies and includes: the Listing Rules; the Financial Services Act 1986 (the "Act"); the Companies Acts; the Insolvency Act 1986; the Criminal Justice Act 1993; European legislation; and other English primary and secondary legislation.

2.2 The Exchange, in its role of Competent Authority for Listing, is only responsible for the Listing Rules.

3. "Is any distinction made between biotechnology companies and other listed companies?"

3.1 The Listing Rules apply to all listed companies. In addition, certain chapters provide rules adding to and/or modifying the general Listing Rules for the purposes of regulating specialised sectors of the market. Biotechnology companies have rules designed to cater for the special needs of their sector at Chapter 20 of the Listing Rules, a copy of which is included as Appendix 2. These rules provide modified conditions for listing biotechnology companies, along with additional requirements relating to the contents of prospectuses or listing particulars prepared for the purposes of seeking admission to the Official List.

3.2 In summary, biotechnology companies do not need to comply with the general condition for listing that a company must demonstrate that it has been carrying on its main activity as an independent, revenue earning, business for at least three years. However biotechnology companies must instead demonstrate their suitability with other conditions for listing, beyond the normal requirements placed on listed companies.

¹ Appendix 3, HC888II, Session 1997–98.

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[Continued

These alternative conditions include:

- the ability to attract funds from sophisticated investors;
- a capitalisation at least £20 million at the time of listing;
- have as the primary reason for listing the raising of finance to bring identified products to a stage where they can generate significant revenue;
- the achievement of significant commercial milestones in the applicant's development as a scientific research based company; and
- the directors and senior managers, collectively, must have the knowledge and experience necessary for the company's activities, including technical, marketing, and, if appropriate, manufacturing experience.

3.3 Chapter 20 further provides that prospectuses or listing particulars prepared by biotechnology companies for the purposes of seeking admission to listing must contain information in addition to that required to be included in prospectuses or listing particulars of other listed companies, including:

- an independent report assessing the company's products and business plan, and any associated risks; and
- details of historic valuations of the company, together with an explanation of any trends in the company's valuation.

3.4 The Listing Rules place a general obligation on listed companies to disclose without delay, via the Exchange's Regulatory News Service, details of major new developments and changes in the company's performance, or in expectations of its performance, which are not public knowledge and which may lead to a substantial movement in the company's share price. The Listing Rules relating to the general obligation of disclosure of price sensitive information apply in the same way to all listed companies, including biotechnology companies.

4. *"Is there a conflict, real or perceived, between the requirements for the disclosure of price sensitive information and the strictures of the various medicines control agencies against the promotion of unlicensed pharmaceutical products?"*

4.1 In their hearings before the Committee, representatives of both British Biotech PLC and Cortecs PLC suggested that there might be a conflict between the requirements of the Exchange and the medicines control agencies. The Exchange understands that this purported conflict is between its own requirements regarding the dissemination by listed companies of price sensitive information (see paragraph 3.4 above) and the medicines control agencies' restrictions on the promotion of unlicensed drugs.

4.2 The Exchange does not consider there to be a conflict. This opinion is supported by both the MCA and the EMEA and is consistent with the Government's Response to the Science and Technology Committee's Fifth Report, 1997–98 Session, on British Biotech (the "Committee's Report").

4.3 Information on the progress of a listed biotechnology company's drug(s) towards market authorisation by the medicines control agencies is potentially price sensitive and may require disclosure under the general obligation of disclosure laid down by the Listing Rules. Further, the information required to be disclosed under this obligation should not be inaccurate or misleading. This does not conflict with the relevant regulations of the medicines control agencies concerning the promotion of unlicensed drugs. In particular, these regulations do not prevent the disclosure by biotechnology companies of factual information concerning the progress of a company's drug(s) towards market authorisation.

5. *"If [there is a conflict], is there any reason why this should be more of a problem for biotechnology-based companies than for pharmaceutical companies developing drugs and diagnostic tools by more conventional means?"*

5.1 While it is the opinion of the Exchange and the medicines control agencies that there is no conflict between their respective regulatory regimes, it is true that biotechnology based companies do face unique pressures that are not experienced by more mature pharmaceutical companies.

5.2 Typically mature pharmaceutical companies have a track record of bringing products to the market and have a portfolio of established products that generate revenue and profits, providing the basis for a traditional valuation of the company. In contrast, biotechnology companies have little or no track record of turning research into products; they float on the promise of future revenue from a limited range of products.

5.3 A biotechnology company cannot, therefore, be valued on a traditional basis. Instead other factors, such as the assessment of the likelihood of a drug successfully coming to the market and its potential commercial value once on the market, are relied on for the purposes of valuation. Consequently the news that a biotechnology company disseminates to the market about its products under development is of

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fundamental importance to both the market and the market's valuation of the company. In these circumstances, the success or failure of a product naturally has a greater impact on a biotechnology company's share price than if it had a number of products already generating revenue and profits.

6. *"Is there a need for greater, or better, communications between the industry and the City?"*

6.1 The Committee's inquiry into the regulation of the biotechnology sector has highlighted the unique pressures that biotechnology companies face, particularly in terms of the demand for and supply of news flow. In order to be able to function on an equitable basis the City requires clear, measured and unambiguous communication of the developments in any listed company's business. These basic requirements are mirrored in the provisions of the Listing Rules, particularly those referred to in paragraph 3.4 above.

6.2 British Biotech and Cortecs are just two of the 41 biotechnology companies currently quoted on the Official List and the Alternative Investment Market. There is no current evidence to indicate that other companies in the sector are experiencing similar difficulties. The Exchange does pursue and will continue to pursue a wide range of opportunities to educate companies and other market participants in the nature and implementation of the Listing Rules.

7. *"What would such an improvement achieve? How could it be done?"*

7.1 The Exchange welcomes any initiative that seeks to improve communications between biotechnology companies and the City. Such an improvement may help to reduce the share price volatility experienced by quoted biotechnology companies. The proposed publication of a voluntary Code of Practice for the biotechnology industry, currently under consideration by the BioIndustry Association (the "BIA"), may assist in this. The Exchange understands that this Code of Practice is due to be put forward for consultation by June 1999 and awaits its recommendations with interest.

7.2 Whilst it is the Exchange's opinion that biotechnology companies themselves together with their advisers are best placed to judge the price sensitivity of information about their own business (see paragraphs 5 and 7 of the Exchange's Guidance on the Dissemination of Price Sensitive Information) the Exchange does encourage listed companies and all its advisors to contact its dedicated help line on 0171 797 3333 with any queries. Further, the Exchange will consider the need to include specific references to the requirements relating to the disclosure of price sensitive information in respect of biotechnology companies when we next update our Guidance on the Dissemination of Price Sensitive Information.

7.3 Chapter 20 was developed in consultation with biotechnology companies and relevant market practitioners and introduced in December 1993. The Exchange is therefore experienced in dealing with biotechnology issues and has continued the consultation process both in terms of providing revised versions of the Listing Rules and in the discussion of day-to-day concerns. Further, as with other specialist sectors, the Exchange has the facility to draw upon expert knowledge when the need arises; we will continue to utilise this expertise.

8. *"The Committee would welcome the comments of the Stock Exchange on the recommendations contained in its Report on British Biotech and the Government's Response. In particular, the Committee would be interested to hear of any developments since its Report was published regarding co-operation between the Stock Exchange and the medicines control agencies."*

8.1 The Exchange can confirm that, following the publication of the Committee's Report, it discussed the relevant recommendations contained therein with the appropriate medicines control agencies. This communication has confirmed the Exchange's opinion at the time of the publication of the Committee's Report that there is no conflict between the medicines control agencies' requirements about the release of information and the obligations imposed by the Listing Rules.

9. *"The Committee would also welcome copies of any guidance issued by the Stock Exchange on the dissemination of price-sensitive information."*

9.1 For the information of the Committee, we enclose a copy of the Exchange's current Guidance on the Dissemination of Price Sensitive Information, referred to above at paragraph 7.2, at Appendix 3¹.

¹ Not printed.

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10. "Please feel free to include any additional information which you think should be drawn to the attention of the Committee in this regard."

10.1 The Exchange investigates listed companies for apparent breaches of the Listing Rules, including breaches of the rules relating to the dissemination of price sensitive information. These rules apply to all listed companies, including biotechnology companies.

10.2 We welcome the Committee's continuing interest in this matter and would be happy to provide it with any further assistance.

28 April 1999

APPENDIX 1

SUMMARY OF THE RELEVANT FUNCTIONS OF THE EXCHANGE

1. We set out in paragraphs 2 to 6 below an explanation of the Exchange's functions, as relevant to the Committee's inquiry, together with a brief summary of the key features of the Listing Rules. This information largely repeats that which was previously provided to the Committee in paragraphs 1.1 to 1.5 of our earlier memorandum dated 7 July 1998.¹

2. Under the provisions of Part IV of the Financial Services Act 1986 (the "Act"), which is based on EU Directives, the Exchange is the Competent Authority for Listing in the UK (the "Competent Authority"). As Competent Authority, the Exchange is responsible for the regulation of companies whose securities are admitted to the Official List. The Exchange also has another regulatory role, as a recognised investment exchange. In this role the Exchange is responsible for regulating the trading of securities quoted on its markets and must satisfy the requirements contained in Schedule 4 to the Act.

3. As Competent Authority the Exchange publishes requirements for listing (the "Listing Rules") which incorporate EU Directives on conditions for listing and minimum standards for disclosure of information. For reasons of investor protection the Exchange can, and does, impose additional requirements that go beyond those laid down by EU Directives. The Listing Rules are designed to promote investor confidence in standards of disclosure, in the conduct of listed companies' affairs and in the market as a whole.

4. The Exchange is also responsible for investigating potential breaches of the Listing Rules. For the purpose of verifying whether there has been a breach of the Listing Rules the Exchange can require a listed company, its directors and sponsor to provide all relevant information or explanations. The Exchange does not have the statutory authority to require other relevant parties to assist it with investigations into potential breaches of the Listing Rules and any co-operation provided by such other parties is provided on a voluntary basis.

5. The Exchange has the power to impose sanctions where it concludes that a breach of the Listing Rules has occurred. The range of sanctions available to the Exchange is limited to censure, either private or public, and, *in extremis*, the suspension or cancellation of the listing of the company's securities. These sanctions can be imposed against the listed company, and/or its directors and/or its sponsor. If the Exchange's executive believes it appropriate to impose any sanction the matter will be referred to the Quotations Committee (an independent body of market practitioners appointed by the Board of the Exchange), save where the company or director concerned agrees to a private censure and the Exchange considers that to be the appropriate sanction.

6. Actions required as a result of an investigation carried out by the Exchange into a potential breach of the Listing Rules may fall outside the ambit of the Competent Authority. In particular, the Exchange's responsibilities do not extend to statutory issues, including criminal law, which fall within the remit of other regulatory and investigative bodies such as the Department of Trade and Industry and the Serious Fraud Office. The Exchange will refer cases falling into these categories to the appropriate body.

¹ Not printed.

*2 September 1999]**[Continued***APPENDIX 2****CHAPTER 20 OF THE LISTING RULES****SCIENTIFIC RESEARCH BASED COMPANIES****SCOPE OF CHAPTER**

This chapter is intended to enable substantial scientific research based companies without an adequate trading record to raise finance by listing their securities if the criteria set out below are satisfied. It is intended for companies which are primarily involved in the laboratory research and development of chemical or biological products or processes, including pharmaceutical companies and those involved in the areas of diagnostics, agriculture and food.

Due to the nature of applications pursuant to this chapter it will be necessary to contact the Exchange at an early stage to discuss an applicant's suitability for listing. The consideration of the suitability of any applicant under the provisions of this chapter may raise issues which will require variations or additions, as appropriate, to the rules set out in this chapter.

The main headings are:

- 20.1 definitions
- 20.2 general
- 20.3 conditions for Listing
- 20.8 listing particulars.

DEFINITIONS

20.1 The following definitions apply:

- (a) a "scientific research based company" is a company which is primarily involved in the laboratory research and development of chemical or biological products or processes and may include, subject to the agreement of the Exchange, other similar innovative science based companies;
- (b) "validations" are tests or trials of importance or significance in assessing the effectiveness or viability of a product of a scientific research based company; and
- (c) a "major shareholder" is a person who:
 - (i) is interested in ten per cent or more of the class of security in respect of which the application for listing is being made (calculated on the assumption that any outstanding warrants or options which have been granted or other convertible securities in issue have been exercised or converted but before taking into account any securities issued at the same time as listing); or
 - (ii) has the right, by virtue of any agreement, to nominate a person to the board of directors of the applicant company.

GENERAL

20.2 The Exchange may list the securities of a scientific research based company which cannot comply with paragraph 3.6 (nature and duration of business activities) if the company otherwise complies with the listing rules as modified by the provisions of this chapter.

CONDITIONS FOR LISTING

20.3 A new applicant to which this chapter applies must satisfy the requirements of chapter 3 except for paragraph 3.6 (nature and duration of business activities) (see paragraph 20.2) and in addition must:

- (a) have demonstrated its ability to attract funds from sophisticated investors;
- (b) intend to raise at least £10 million pursuant to a marketing at the time of listing;
- (c) have a capitalisation, prior to the marketing at the time of listing, of at least £20 million (based on the issue price and excluding the value of any securities which have been issued in the six months prior to listing);
- (d) have as its primary reason for listing the raising of finance to bring identified products to a stage where they can generate significant revenues; and
- (e) demonstrate to the satisfaction of the Exchange that it has achieved significant commercial milestones in its development as a scientific research based company, which will normally include at least one of the following:

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- (i) if it is a company whose activities are mainly the research and development of pharmaceutical products, having at least two drugs in clinical trial under internationally accepted regulatory scrutiny;
- (ii) if it is a company engaged in the research and development of non-pharmaceutical products, having made equivalent progress through appropriate trials under regulatory or official scrutiny;
- (iii) having entered into a current development agreement or agreements with one or more independent companies pursuant to which non-refundable payments amounting to not less than £5 million have been received or unconditionally committed and under which the scientific research based company retains a significant financial interest in any intellectual property created; or
- (iv) having incurred expenditure amounting to not less than £20 million in research and development over a period of not less than three years which has demonstrably resulted in the creation of intellectual property of significant worth which the company intends to develop as its main business activity.

20.4 For the purposes of paragraph 3.8 (directors), the directors and senior managers of the company must be able to demonstrate that they have, collectively, the knowledge and experience necessary for the company's activities, including technical, financial, marketing and, if appropriate, manufacturing experience. In particular, the board of directors and senior managers must include at least one executive director or senior manager who has been responsible for the company's research activities throughout the period covered by the accounts required by paragraph 3.3 (a) and must include other persons who have played a significant role in the company's activities throughout the relevant period.

20.5 The company must ensure unless otherwise agreed by the Exchange that:

- (a) all persons who are, at the time the application for listing is made, or were, within the 12 months preceding such application, directors, associates of directors (as defined in paragraph 11.1(d)), senior employees and associates of senior employees of the company (and, if different, its principal operating subsidiaries) agree not to dispose of any, or any interest in, relevant securities in the company (other than amongst themselves), either at the time of listing or for a period of two years from the date on which dealings commence;
- (b) all major shareholders agree not to dispose of:
 - (i) any, or any interest in, relevant securities in the company either at the time of listing or for a period of six months from the date on which dealings commence or, if longer, during the period prior to the publication of the first half yearly or annual results following the date on which dealings commence; and
 - (ii) subject to (i) above, more than 40 per cent of their respective holdings of any relevant securities for a period of two years from the date on which dealings commence;
 other than amongst themselves or to those persons described in sub-paragraph (a); and
- (c) sales of any relevant securities at the time of listing by holders other than those described in sub-paragraphs (a) and (b) do not exceed 20 per cent of the total number of relevant securities the subject of the marketing.

20.6 For the purposes of paragraph 20.5, the term "relevant securities" means shares, convertible securities, options, warrants or similar instruments held immediately prior to admission to listing and any shares arising from the conversion of any such convertible securities or the exercise of any such options, warrants or similar instruments.

20.7 *Paragraph deleted—August 1995*

LISTING PARTICULARS

20.8 The listing particulars of a new applicant under this chapter must comply with the requirements of chapter 5 and must:

- (a) demonstrate that the company has at least a three year record of operations in laboratory research and development including:
 - (i) details of patents granted or details of the progress of patent applications; and
 - (ii) in relation to its products the successful completion of, or the successful progression of, validations;
- (b) demonstrate that the operations referred to in (a) above are supported by directors and technical staff of appropriate expertise and experience and that those directors and technical staff are reasonably expected to remain available to the company;

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- (c) contain an estimate of its funding requirements for a period of two years following the listing and state that these requirements can be met, under current estimates, from existing resources and from the proceeds of the issue of securities made at the time of the listing;
- (d) contain a detailed explanation of the company's business plan;
- (e) contain details of the agreement not to dispose of the shares referred to in paragraph 20.5;
- (f) state that the proceeds of the issue of securities made at the time of the listing, together with the company's existing resources, will be applied primarily towards progressing identified products to a stage where they can generate significant revenues and explain in detail the uses to which the monies will be applied;
- (g) demonstrate that the company has engaged in collaborative research and development agreements with organisations of high standing and repute within the industry or that it can establish that the absence of such agreements does not reduce the standing or quality of its research efforts;
- (h) fully set out, explain and give appropriate prominence in presentation to the risks associated with the exploitation of its products; and
- (i) contain a prominent statement confirming that the company is making its application for listing under the provisions of this chapter.

20.9 The listing particulars must also give, in relation to each of the new applicant's products the development of which may have a material effect on the future prospects of the company, a full description of:

- (a) the type of product being developed;
- (b) the expected advantages of the product including any appropriate technical information;
- (c) the nature and effectiveness of the research and development undertaken;
- (d) the development status of the product including the results of validations (see also paragraph 20.10);
- (e) in relation to any product undergoing validation, any material information relating to the prospects of the successful completion of such validation;
- (f) the exact status of the patent position, to include details of the nature of the applications filed, the expected timetable in relation to any patents pending and the potential impact of any significant prior applications by third parties;
- (g) the copyright position in relation to any software which is a part of or connected with the product;
- (h) the current or expected market competitors;
- (i) the basis of any claimed market potential; and
- (j) the future strategy of the company regarding the generation of significant revenues from the product, including:
 - (i) whether the company intends to implement the strategy itself or in collaboration with others;
 - (ii) where the company intends to undertake such activities itself, its plans in relation to the manufacture and marketing of the product;
 - (iii) where the company intends to collaborate with others in relation to the implementation of the strategy, details (including the consideration and parties) and the financial effect of any agreement or intended agreement; and
 - (iv) if the strategy varies according to the expected major markets for the product, an explanation of any geographical or segmental variants.

20.10 For the purposes of paragraph 20.9(d), details must be given, in relation to each product, of all material:

- (a) internal validations of the product by the company;
- (b) external validations of the product by independent third parties;
- (c) validations by regulatory authorities; and
- (d) academic papers in relation to the product.

Independent report

20.11 The listing particulars must include a report or reports by an organisation or organisations assessing:

- (a) the merits of the company's products;
- (b) the company's business plan, including the critical path and timescale to commercial exploitation and any projections of the market potential for the company's products; and
- (c) the risk factors which might affect the company's business plan.

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Each report must also include a summary of the instructions pursuant to which it has been prepared. Each reporting organisation must be independent of the company and be of demonstrable high standing, repute and expertise in the field concerned and must confine the opinions expressed to matters within its expertise.

20.12 *Paragraph deleted—August 1995*

Valuation

20.13 The listing particulars must include details of:

- (a) the historic valuation of the company at each fund raising undertaken, giving the date, price, amount and principal terms of the fund raising, presented in tabular form and prominently set out in the particulars;
- (b) any other recent valuations, including details of trades, on any market; and
- (c) a full explanation of any trends in the valuation of the company, justifying, to the satisfaction of the Exchange, any substantial increases in valuation.

Examination of Witnesses

MR PAUL GERADINE, Head of Listing Department, and MS MARIA CLOHESSY, Head of Company Monitoring and Enquiries Group, Listing Department, The London Stock Exchange, were examined.

Chairman

54. Mr Geradine, Ms Clohessy, thank you very much for joining us this morning and helping us with the inquiry we are completing into regulation of the biotechnology industry. I did notice that you were in the public gallery during the course of the earlier witness session, so I think it would be in order to refer to that earlier witness session if you wish to during the course of your evidence. Although I think we know you both already, would you care to give us just a very brief introduction of yourselves so that it can be put into the record.

(Mr Geradine) Certainly. I am Paul Geradine, I am the Head of the Stock Exchange's Listing Department. Just to explain very briefly what the Listing Department's responsibilities are. Primarily we are responsible for the admission of new companies to the London Stock Exchange's markets and also for the listing of any further shares which existing listed companies may issue. Perhaps most important from the point of view of this hearing, we also have responsibility for monitoring the ongoing requirements which we impose on existing listed companies, what we refer to as the continuing obligations. Not only monitoring those but, where there are apparent breaches, investigating them and if necessary taking enforcement action. My colleague, Maria Clohessy, heads up our Company Monitoring and Enquiries Group within the Listing Department and it is that group which has specific responsibility for the monitoring and enforcement operations.

55. Thank you very much indeed. As usual we will direct our questions to you, Mr Geradine, but if you wish to pass them to your colleague, or invite your colleague to speak, we would be most delighted. If Ms Clohessy wishes to speak, uninvited by Mr Geradine, if she just indicates we will ask her to do so.

(Ms Clohessy) Thank you.

56. Perhaps I can just start off by asking whether you support the introduction of a Code of Practice governing the management of information for biotechnology companies of the type that you have heard about this morning?

(Mr Geradine) The answer to that is an unequivocal yes. We see the steps taken by the Bioindustry Association in publishing this Code as a very helpful supplement to our own Listing Rules, specifically in the area that the BIA has identified of handling, publishing and communicating key information. More particularly I think what it achieves from our point of view is it will raise going forward awareness of these vital issues of communication in respect of biotechnology companies. We have been very grateful to the BIA for giving us the opportunity prior to the publication of the draft Code of seeing a couple of draft proofs in advance of publication and for meeting with us and discussing our comments. We have also given them some further feedback having had a longer period throughout the consultation period to reflect on the precise drafting of the Code. We very much welcome this Code as raising the awareness of some very important regulatory issues in this specific sector.

57. The investors in biotech companies can be large investors, large institutional investors, or indeed small private investors, but even the large institutional investors could be representing small people in the sense that they might be—what is it when you have all these things conglomerated together, I cannot think of the word.

(Mr Geradine) Mutual funds?

58. Mutual funds, yes. Can you tell us how this Code will help those who invest in the biotech industry to have more confidence that their investment is going to be treated with integrity?

(Mr Geradine) The issue of provision of information, in particular the timeliness and completeness of information, by any listed company is absolutely essential from the point of view of its valuation in the market and obviously investment decisions that investors large or small then take. The importance of that information, as Mr Mansfield

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MR PAUL GERADINE AND MS MARIA CLOHESSY

[Continued]

[Chairman Cont]

was referring to earlier, is perhaps even greater for biotechnology companies than perhaps other sectors of our market because clearly early stage biotechnology companies do not have the revenue earning history, the product history that more established companies do. In the absence of information about revenues and the history of successful product sales, clearly information about product development is absolutely vital. So this Code in raising awareness of the importance of issues about communicating information of product development should give great confidence to investors that this major issue for biotechnology companies is being firmly addressed by all those involved.

59. I would like to ask you more about how you have been involved and what you would like to see changed but I know Dr Gibson is going to ask that in just one minute. Can I just put my final question to you? In your memorandum you acknowledge that there are, to use your own expression, "unique pressures" for biotech companies that are not experienced by the more mature pharmaceutical companies. This is in relation to managing the flow of price sensitive information. Could you let the Committee know how you think this Code of Practice that we have heard about this morning and that we have read about over the last several weeks will help the smaller companies to withstand the pressures that we have just talked about?

(Mr Geradine) Going back to some earlier comments that I was making, what this Code will do is it will raise the overall awareness of the fundamental importance of this issue for biotech companies both large and small. Clearly these issues are already addressed in our own Listing Rules. I think the real value in this Code is in raising the overall awareness of just how important this issue is. Does that address your question or was there a slightly different element to it?

60. It is just that I thought that big companies by and large can look after themselves but smaller companies, and you acknowledged this in your submission, have unique pressures and that unique pressure that you were referring to might well be if a company is smaller it will not have perhaps as much direct linkage to its investors and it will not necessarily have someone managing information, it is more likely that there will be a leakage due to somebody in the company being enthusiastic in talking to somebody else. All of those things could be linked to small companies, that is what I thought you might be thinking about.

(Mr Geradine) Sure.

61. Therefore, I wonder how it is that this Code will help those small companies rather than the large ones who might have their own inhouse codes already. I had expected some sort of answer that the big companies will have the in-house codes and small companies will not, that this is a collective Code for the small companies without in-house regulation.

(Mr Geradine) Clearly what in particular Principles One, Two and Three of this Code do for those companies, and some large companies do not have all of the expertise that they require in-house, both in the biotechnology sector and in other sectors,

is raise the awareness of the importance of having a balance on the Board, having the appropriate scientific expert advice and ensuring that there is a good flow of information through to the Board. It will raise that awareness across the sector, including for these small companies.

Dr Gibson

62. The obvious question is why did this not happen before? Is it part of your job to look at burgeoning new companies like in the biotechnology industry? Were there no red lights flashing because there were no products; people were suspicious; there is now an anti-biotechnology culture out there and so on? Did you not see all of this coming or is it not your job to look at that? You are reacting to the events of 1998 really and saying: "fine, good", but why was it not picked up before that these problems were going to arise?

(Mr Geradine) We fully accept that companies need both regulation and guidance in terms of the flow of information. I am not just talking here about biotech companies. That is precisely why we have set down for many years rules requiring complete and timely release of any information which may be price sensitive. In addition to that, Dr Gibson, what we have done in more recent years, and I am talking about 1995-96, is we have given companies much more wide ranging guidance. I think we have provided the Committee previously with a copy of our guidance on the dissemination of price sensitive information. We fully recognise the importance of this issue for companies across all of the 50 to 60 sectors we have in our markets, not just the biotechnology companies. Yes, it is a very important issue and one we have been alive to in the market in general for many years, hence the monitoring and enforcement operations that I mentioned a few moments ago.

63. That you are very keen on this Code is a start, but surely it does not go far enough? Biotechnology companies in California fall out of the system every day and new ones are created and it is a very volatile area and all sorts of things can go wrong. Where do you see some regulation being tighter than just a code, guidance notes which people can just basically ignore really and just put a couple of lines in their annual report? How tight are you going to be on them and what kind of regulation do you perceive is going to be needed beyond what we are talking about here today?

(Mr Geradine) First and foremost, not to belittle the problems which there have been which have been substantial, we have 2,500 to 3,000 companies quoted on our markets and what we are talking about here is one specific company and potentially a couple of others and we have very effective regulation and, as I said, monitoring and enforcement operations already in place which the vast majority of our companies on our markets respect consistently and work with consistently. Now, turning specifically to the point you have made, we have all learnt lessons out of these recent experiences, we have already embarked on work to update our guidance and there will certainly be things for us to incorporate into that revised guidance from BIA's own work. Taking your

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MR PAUL GERADINE AND MS MARIA CLOHESSY

[Continued

[Dr Gibson Cont]

point about regulation, there is also something for us to learn there and we will be publishing in a couple of weeks' time our annual consultation document on changes to the Listing Rules and one particular area of the Listing Rules previously covered in our guidance which has now been brought together into the rules themselves is making it quite clear that companies must produce balanced, ie, not misleading, statements to the market, so clearly there is something for us to learn as well.

64. Are there any lessons from the United States because scientific journals are full of information about biotech companies fighting each other over patent rules and so on? It is an extremely volatile industry. How do you get hold of and control it? It is probably not like anything else you have had in the past before and the British Government is very keen on it, and clusters may be developing everywhere; start-up companies here and there by entrepreneurial types will not make it and so on; but might get listed unless you regulate it and control it in a determined way.

(Mr Geradine) Absolutely, and I think, taking Mr Mansfield's point of earlier, your point attracts added significance because clearly what we are seeing now are early-stage technology companies coming from other technology sectors, not just the biotechnology sectors, so clearly it is vitally important that these companies are effectively regulated. My direct answer to your question is that I believe that these companies are effectively regulated already and what we see the particular value of the BIA Code as doing is raising still further the awareness of these regulatory issues in the biotechnology sector specifically, so I firmly believe that effective regulation and monitoring and enforcement operations, which we have considerably developed in recent years, already exist to address these regulatory concerns.

Mr Beard

65. You just said then that you believe that these companies were adequately regulated already, but in the case of British Biotech, for instance, there were some very optimistic statements put out which were not entirely in keeping with the state of things, which you could have said were misleading and yet the Stock Exchange regulatory arrangements did not pick those up until there was a disaster virtually.

(Mr Geradine) What the Stock Exchange has done is identified at an early stage a potential problem at that point with British Biotech, namely we identified an issue there on the back of the announcement of, I think it was, the suspension of Dr Miller in March of—

66. That was a long way down the track.

(Mr Geradine) Sure, but, going back to the point I was making to Dr Gibson, what we have already had in place is requirements on the companies to release without delay all potentially price-sensitive information and, as I said, the vast majority of listed companies have no difficulties in complying with our requirements. Clearly as with any set of laws or regulations, the existence of those laws or regulations cannot prevent wrongdoing. What the Exchange did

on a very timely basis when the problems with British Biotech emerged was take exactly that sort of enforcement action resulting in our statement in June this year.

67. But, to be fair, you took action at a stage when the problems were obvious. Would it not have been reasonable to have expected action to have been taken when they were not so obvious to the general public, but were to the insiders monitoring the position because information was being put out which, to put it mildly, was not entirely congruent with the balance of reasonable interpretation and the results of tests?

(Mr Geradine) Well, everybody involved in any kind of legal or regulatory enforcement work would prefer to identify problems at the earliest possible stage. What I am basically saying is that one can never devise laws or regulations which will completely prevent wrongdoing. What one is obviously relying on is the integrity of individuals responsible for complying with those laws and regulations.

68. Could I just go back to a point that Dr Gibson has touched on already and that is where you in the Stock Exchange are regulating listed companies in the biotech sector, is there a regulation which you apply comparable with regulation in the United States?

(Mr Geradine) Yes, I believe it is because the Securities and Exchange Commission in the United States has similar requirements to our own to require companies to release potentially price-sensitive information without delay.

69. Do you see it being in any way tougher in the requirements and its monitoring procedures than you are?

(Mr Geradine) No, I do not. I believe, as I have tried to make clear already, that our monitoring and enforcement operations are extremely effective.

70. This draft Code which really is carrying regulations into an area which is beyond your ken, so to speak, it is beyond the requirements of the Stock Exchange, do you think it is comprehensive enough?

(Mr Geradine) Yes, what the BIA has done here is it has set itself a scope with this Code which is basically, as I said earlier, the handling and publication of information and I think within that scope it is extremely comprehensive.

71. Do you have any observations on this distinction between principles and provisions and whether those distinctions are actually somewhat muddying the water a bit?

(Mr Geradine) That is a distinction which we are already familiar with from the work of Sir Ronald Hampel's committee on corporate governance generally which was published last year. I believe that it is a very helpful distinction to draw out, if you like, the sort of broad issues in the principles and then, I think Mr Mansfield's word earlier was, to "exemplify" the application of those principles through Code provisions, so, if you like, highlighting the major issues in the principles is, I think, a very valuable distinction to draw.

72. So you believe that this is a very clear statement of what is required by a biotech company?

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[Continued]

[Mr Beard Cont]

(Mr Geradine) Absolutely in respect of, as I say, the handling of information, yes.

Dr Jones

73. To go back to what we were saying about British Biotech, when do you think the Stock Exchange would have picked up the problems if there had not been a whistle-blower inside the company?

(Mr Geradine) As I have said already, the way we picked it up first off was when the company made an announcement about the suspension of Dr Miller.

74. Yes, exactly.

(Mr Geradine) That was obviously before Dr Miller took his allegations to the press. What we have in place is a series of public information services at the Stock Exchange to which members of the public can refer any concerns they have about companies' compliance with our listing requirements, so there is that route for people to disclose information to us and there is obviously—

75. But, as you know, there is an awful lot of pressure on those who will have that knowledge not to disclose, so how will the Code help to ensure that they do come forward and give the information?

(Mr Geradine) I think what this Code does very importantly is, as I have said already, it raises the overall awareness of the importance of these issues particularly for biotechnology companies. So it is likely going forward that those involved in the biotechnology industry, whether as directors, employees, investors or advisers, will have an even clearer idea of the implications for their specific companies.

76. Do you not think Biotech were aware when they put out press releases which were optimistic that they had problems with the Medicines Control Agency and yet they went ahead and put out those press releases? Surely they must have been aware but they still did it.

(Mr Geradine) You will have seen our public statement of criticism in respect of British Biotech which makes it quite clear that we have concluded that in respect of the Zacutex drug programme the statements that British Biotech made, and indeed failed to make, did mislead the market. In terms of other information about British Biotech, Chairman, if I can make one general point which is clearly we have written to this Committee previously under statutory confidentiality obligations and I would be very happy to deal with any specific matters on British Biotech outside of our existing public statement in writing to the Committee but obviously in this meeting I am constrained in what I can say.

Chairman: I think that is right, you are constrained in what you can say. There is Parliamentary Privilege but it is something we do not wish to use too frequently. I think the principle that Dr Jones is asking you about is how would the Stock Exchange know that something was amiss if it was not for the fact that the problem was being trumpeted pretty loudly in the press? That is the general question that could be answered without referring to any company at all.

Dr Jones: Can I just say you seem to be pinning your hopes on raising awareness but the chief executive of Biotech was advising the Government on biotechnology. How more aware do you have to be, and yet it still happened.

Chairman

77. In your response please follow my invitation not to refer to any one company but to talk about the problem in general.

(Mr Geradine) What we do within our Listing Department in terms of monitoring companies' operations is we look at all unusual announcements that companies put out. To the extent that any of those unusual announcements raise concerns that there may be a breach of the Listing Rules we will start to investigate that company and ask for information from that company immediately. The key first step in that is what does the company announce to the market? Clearly if what the company announces to the market appears to be a perfectly normal announcement in the ordinary course of its business then there will be nothing to alert the Stock Exchange or any other agency to a potential problem in that company. That is why I came back earlier to clearly anybody involved in regulatory or enforcement work does have to rely to a large extent on the integrity of the individuals who are responsible for applying the regulations.

78. Can I just ask you a question. Many analysts, if not all, who will follow the sector of the industry listed in the Stock Exchange, become pretty proficient in understanding the sector that they are monitoring. Do you think that it would be usual or not usual for an analyst that saw a statement that flew contrary to all his or her knowledge of that industry not only to go to his or her boss in the Stock Exchange but would it be likely that they would come to the Stock Exchange *per se* and say: "there is something happening here that we think is not consistent with what we know of the company"?

(Mr Geradine) It has happened but I would be misleading you if I said it happened on a regular basis. I would also add, as I have said earlier, the vast majority of our listed companies we have no compliance concerns with in terms of how they abide by our Listing Regulations.

Mr Beard

79. Could I put the question another way, the question that I think is concerning all of us on this side of the table. In relation to British Biotech there were optimistic press releases put out long before Dr Miller resigned and yet that was not spotted by the Stock Exchange and to a degree they were out of line, they were providing misleading information for investors. The question that we are really probing is what is going to be different in the future from that? Would that recur? If there was an equivalent situation now somewhere out there in the clouds would you be able to spot it more easily than you were able to spot the previous instances of this?

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[Continued]

[Mr Beard Cont]

(*Mr Geradine*) As I have said already, we have high quality monitoring operations already in place. What those monitoring operations cannot pick up are statements that are, if you like, designed to mislead.

Chairman

80. I am not going to try to force you to give me a yes or no, I think that is unfair, but I would like you to give us an answer that is a bit closer to yes or no than your last one. In answer to Mr Beard's question, do you think that you are any better prepared to pick up on misleading statements that will happen in the future than you were in the past as a result of this Code of Practice?

(*Mr Geradine*) I will answer that directly by saying yes because, as I made the point in response to Dr Gibson's question earlier, we have learned about one specific area of our regulations which requires amendment and we will amend it. Indeed, as I have said previously, we will take into account the lessons from the biotechnology industry in revising our guidance on dissemination of price sensitive information.

Dr Jones

81. What sort of contact have you had with the Medicines Control Agency and the European Agency? Obviously they will be working with the company in terms of development of a new product. Do you liaise with them over the work that they are doing?

(*Mr Geradine*) Prior to the case involving British Biotech, no, there has not been any liaison. Clearly in respect of that particular case there was and there will be in respect of future problem cases. Indeed, we will make it clear to both of those agencies and to others that we will be very interested to hear concerns they may have about biotechnology complying with our Listing Rules.

82. It is unlikely that the medicines control bodies will be looking at press releases, whereas you will be looking; that is your area. Should there not be formal collaboration over these areas?

(*Mr Geradine*) I disagree slightly with one point there which is that both the EMEA and the MCA will look at press releases because they are concerned that companies should avoid any promotion of products prior to the product authorisation application having been concluded. Clearly there is scope for them to identify potential problems and, as I say, what I hope we can do is establish even closer relations with them going forward.

83. They are looking at different aspects, are they not, from you? Should there not be some formal arrangement over these matters rather than just "we are hoping for greater collaboration"?

(*Mr Geradine*) As I have said already, that is an issue that we want to pursue with both of those bodies.

84. It is now a long time since all of this came to a head and you still have not sorted anything out.

(*Mr Geradine*) It is only a short time since we concluded our investigation into British Biotech, that was only concluded in June.

Dr Gibson

85. Do you agree with me that biotechnology and the Code that is now related to it is no different from any other industry from your point of view? The food industry has all sorts of codes attached to it too. Basically you trust everybody until something comes up, whereas some of us might go the other way and distrust them all. Is that your philosophy?

(*Mr Geradine*) No, Dr Gibson. If I trusted everybody I would not have a monitoring and enforcement operation.

86. That is why you should never trust a biotech company just through a Code.

(*Mr Geradine*) We do not just trust them through a Code. As I have said, we have got our own regulations in place.

87. What about the poor shareholder in the biotechnology industry? If I had £5 million of Gordon Brown's money and wanted to invest it in something—with the share volatility as it is now in the biotech industry and in certain aspects of some of the biotechnology companies, "do not invest in them" is the advice that certain banks have been giving as you know, and that has been in the media—how is this Code going to make any difference whatsoever in the share volatility that is associated with this sector? Why should a shareholder want to invest in this industry because there is a Code?

(*Mr Geradine*) I am not an investor in this industry myself so I cannot speak with any direct experience.

88. But you know some people who are.

(*Mr Geradine*) All I can do here is go back to my previous point about awareness because what this Code will do is it will raise both in investors' minds, directors' minds, employees' minds and advisers' minds, more directly the key questions about the flow of information from biotechnology companies into the market even more directly than those issues have been there in the past.

89. So in your professional experience a code makes that difference and guidance notes make a difference?

(*Mr Geradine*) I would say any form of publication must help to raise the overall awareness of issues. As I have said already, we have already addressed these issues in terms of general regulation—

90. What about confidence? Awareness is one thing, but confidence in putting your money into a company is another. Is it going to make any difference to confidence?

(*Mr Geradine*) Well, as I have said, by raising the awareness and through the awareness I think even greater compliance with our list of requirements, that indirectly will lead to an increase in confidence, I hope.

91. Is that a judgment or can you give any evidence?

(*Mr Geradine*) It has to be a judgment, Dr Gibson, because there is no real evidence.

92. Exactly, so we could be suspicious of it in our judgment?

(*Mr Geradine*) You could have your opinion, but, as I said, I believe that through raising awareness, confidence should increase.

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[Continued

Dr Jones

93. Do you think that a company that states it is in compliance with this particular Code of Practice or perhaps any other code of practice will affect investment decisions?

(*Mr Geradine*) I think that is quite possible, yes, because clearly if a company is saying: "No, we don't comply with X, Y, Z principles of this Code and indeed some of the Code provisions", I would have thought that would raise some very serious questions in investors' minds as to why not.

94. What I am talking about is a company that puts in its annual report that it is in compliance with this Code of Practice and do you think that is likely to make investors think that they are more likely to invest in that company or not?

(*Ms Clohessy*) I think we heard earlier on Mr Mansfield say that he had liaised with a number of institutional investors and fund managers about their feelings on the Code and we understand that the feedback, the soundings he has had say that the Code will be well received. I think taking that into account perhaps suggests that investors will take compliance with the Code as a serious issue and perhaps base their investment decisions on that element, although there are of course a whole variety of investment criteria.

Mr Beard

95. What measures are there in the Code of Practice, not duplicating the Stock Exchange Code of Practice, that could have prevented the damaging episodes of British Biotech in 1998 and of Cortecs? What specifically in the new Code could have stopped those things happening?

(*Mr Geradine*) I would just give a general comment which is, as I have said, that any form of law, regulation or code of best practice cannot prevent a course of action if responsible individuals are determined to take that course of action. What I think this Code will achieve through each of principles 1 to 8, which do seem to be directed certainly at events that we dealt with in British Biotech, and I hesitate to use the word again, but what those principles will do is raise the whole market's awareness of the importance of those particular issues.

96. But is there any specific point, either in the principles or the provisions, that would have addressed the specific issues arising in British Biotech and Cortecs?

(*Mr Geradine*) I think there are two particular principles that I would draw the Committee's attention to here. One is principle 4 which requires there to be balance in the information that the company puts out and to ensure that the information is not misleading and, similarly, principle 8 which then deals specifically with the flow of information into the market during the course of regulatory approval by the medicinal regulatory bodies, so those two particular principles, if you like to single out some, are particularly relevant to certainly the British Biotech case.

97. The other question is not in general because I understand what you are saying in general that the existence of a code concentrates people's minds no end, but there were specific circumstances in British Biotech and in Cortecs and specific people dealing with those certain circumstances. Would the existence of this Code have affected their behaviour had it been there, not generally, but their behaviour as you know it from the investigations you have carried out?

(*Mr Geradine*) I think that is an enormously difficult question to answer because clearly all I can do is to speculate about individuals' motives. What I can say is that clearly any individual will have to ask him or herself even more questions in the future by virtue of the existence of a public body of guidance in the form of this Code before deciding to go down a different path.

98. So the answer is really no?

(*Mr Geradine*) As I said, all I can do is speculate about how an individual would take a particular decision.

Dr Gibson

99. Is it the Stock Exchange's position that codes should be monitored; and what experience have you got of that in other areas, the food industry or whatever where there are lots of codes of practice and they are monitored; and in this case are there lessons still to be learned by this industry?

(*Mr Geradine*) The direct answer to your question is that in terms of sector-specific codes, no, we do not monitor compliance with those because, as I have already said, there are Listing Rules for general application across 50 to 60 industry sectors. There is one rider to what I have said which is that after the Hampel committee's Code on Corporate Governance, we do require statements as to how a company has complied with that for the simple reason that that again applies across the full range of UK quoted companies.

100. So not just in the annual report, but a separate statement on that issue?

(*Mr Geradine*) There is a statement required in the annual report and that is how we would monitor whether or not companies are disclosing their compliance with that code.

101. But they can say any old rubbish in an annual report, and they do.

(*Mr Geradine*) And to the extent that it is "rubbish" in that, we would pursue that.

Dr Jones

102. Going back on that point, a few moments ago you said that companies' statements that they have complied with the Code of Practice would affect investment decisions and yet there is no monitoring of that Code, so is that not a problem?

(*Mr Geradine*) Sorry, but could you just repeat that question?

103. Ms Clohessy said that she felt that a company that stated that it was in compliance with this Code of Practice might perhaps get more favourable

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MR PAUL GERADINE AND MS MARIA CLOHESSY

[Continued

[Dr Jones Cont]

treatment from investors and this would plainly be the case and it would affect investment decisions and yet there is no monitoring of such statements, so is that not a problem?

(*Mr Geradine*) There is monitoring as to whether or not a company is making a statement, and I am talking about the combined Code of Corporate Governance here, and, as I was just saying to Dr Gibson, clearly if companies made absurd statements in their annual reports, we would pursue that.

104. How do you know if it is absurd? If they say they are complying with the Code and there is no monitoring of all the provisions, then unless somebody who is in the know actually discloses the information, how does the Stock Exchange or the Bioindustry Association know whether it is in full compliance or not?

(*Mr Geradine*) Well, in the first instance here I am just talking about the combined Code of Corporate Governance. We would use our professional judgment about that statement and then investigate it, and we have powers to require information to be delivered from companies.

105. So you do not think there should be full monitoring by either the Stock Exchange or the industry itself of this Code?

(*Mr Geradine*) We are talking now about the BIA Code?

106. Yes.

(*Mr Geradine*) As I have said, in terms of the industry-specific codes, we do not monitor those because very largely, and this includes the BIA's draft Code, they deal with matters outside of the Stock Exchange's own regulations.

107. But does it not worry you that there is no monitoring even though compliance could affect investment decisions?

(*Mr Geradine*) What there is monitoring of is areas where the BIA's Code addresses and, as I said earlier, supplements the Exchange's own listing requirements. We monitor compliance with those listing requirements.

108. Do you think the sanctions that the BIA can impose on its members who are in breach of the Code, ie censure or expulsion, are strong enough to make the Code effective?

(*Mr Geradine*) That is a question that I think is better addressed to Mr Mansfield.

(*Ms Clohessy*) I was only going to add that the Exchange also has the power to publicly censure companies and we do so. That is taken very seriously by the market place. If the BIA also has that power then it perhaps is not unreasonable to suggest that may be taken seriously.

109. So you are saying from your own experience of when you apply a censure it is effective?

(*Ms Clohessy*) It is.

110. And that should be the case here. What are the ramifications for a company that receives a censure from the Stock Exchange?

(*Ms Clohessy*) There is obviously an impact on its reputation and potentially investors may feel wary about that company depending on the particular nature of the breach.

Dr Gibson

111. Do you fine them as part of that?

(*Ms Clohessy*) We currently do not have the power to fine but it is a power that we have looked for and under the new Financial Services and Markets Bill it is a power we believe we will be getting going forwards.

Dr Jones

112. Have you actually monitored the impact on companies that are censured, what happens to them in the long term and how effective that actually is?

(*Ms Clohessy*) What I can say is that censures which occurred some years ago are still talked about, people mention them to me even now. People do not have short memories, they do remember these things.

113. Can you give me an example?

(*Ms Clohessy*) I will have to give you one outside.

Dr Gibson: Give us a black list.

Chairman

114. Perhaps you can give us an example when this formal hearing is closed. Thank you very much. Mr Geradine, did you want to add something?

(*Mr Geradine*) No, it was exactly the point that Ms Clohessy covered.

115. A final question from myself. Do you think that the Stock Exchange consider making compliance with the new BIA Code of Practice a requirement for British biotech companies who are seeking listing on the official list or the alternative investment market list?

(*Mr Geradine*) As I was saying a few moments ago in response to Dr Jones' question, that is not something that we intend to do. We wholeheartedly support the Code but because our rules have general application across a whole range of industry sectors it is not our intention to require compliance with this Code not least because it also deals with matters outside the range of the Listing Rules but, of course, we do have the monitoring operations in respect of the rules that the Code does cover.

116. Let us take a hypothetical case. If there were a new industry of some type in the next millennium that we cannot anticipate at the moment, high tech, and it has got possible high rewards but it has also got high risks, and it all starts going wrong and again there is a Code of Practice brought in to try to monitor it, you still would not require that Code of Practice to be adhered to before you listed those companies because you have your own system and you do not want your own system adulterated by anyone else's system or anyone else's Code of Practice?

(*Mr Geradine*) It is not that, Chairman, it is that our own system is very effective. What we see this Code of Practice as doing is not fundamentally changing the regulations that we have got but actually explaining those regulations in the context of biotechnology companies as well as dealing with some matters outside of the scope of our rules.

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[Continued

[Chairman Cont]

117. We are coming to an end now and you leave us with a tantalising view of your own system being effective, whereas I think we have shown during the last three-quarters of an hour that your own system was not too effective in 1998 in the two companies that we have been looking at. I think you will continue looking at your own system in the coming years and I think we shall continue watching you watching your own system. We may have to ask you to come to us again and see how effective your new system is. We wish you well, we hope your system does work, but our job is to invite you back if we think that it is not. I hope on that friendly conclusion of our discussions you will understand that we are both on the same side but, whereas you are checking on others, we are the people who check on you.

(Mr Geradine) Thank you. We would be delighted to help the Committee at any point in the future. Obviously what we are trying to look at is a full range of 2,500 to 3,000 listed companies.

Chairman: I understand; it is a very big job. We are grateful to you for coming here today, and Ms Clohessy too. We thank you for the contribution you have made to this Select Committee both in the past and today. We probably will have dialogue or correspondence in the future. We thank you for the contribution you have made and the report that we shall produce very shortly I hope will be of some interest to you. Thank you both very much indeed.

Letter to the Clerk of the Committee from Mr Paul Geradine, Head of Listing, the London Stock Exchange, following the Evidence Session of 2 September

REGULATION OF THE BIOTECHNOLOGY INDUSTRY

I am writing further to last Thursday's hearing before the Science and Technology Select Committee (the "Committee"). We were asked to supply details of public censures that have been particularly noteworthy. Set out below are brief summaries of some of the more notable examples of public censures.

1. London International Group PLC was censured on 14 May 1993 for its disclosure of price sensitive information relating to its expectation of profits to selected analysts prior to informing the market as a whole.
2. Prudential Corporation PLC was censured on 15 March 1995 in relation to the share dealings of certain directors immediately prior to the publication of a report by the SIB on pensions misselling by the insurance industry.
3. Mr Rupert Galliers-Pratt, Chairman of Optical Care (Bermuda) Limited, a company quoted on the Alternative Investment Market ("AIM"), was censured on 24 July 1996 for failing to disclose in the document prepared in connection with the company's admission to AIM, details of all his current directorships and details of his past directorships of companies that had gone into receivership or liquidation within 12 months of his being a director.
4. Clondalkin Group PLC was censured on 29 August 1996 for a breach in relation to a circular to shareholders dated 31 May 1996 regarding its proposed acquisition of the Van der Windt Group. The circular was issued to shareholders without the approval by the Exchange prior to posting. In addition the circular failed to contain an opinion from the reporting accountants on the financial information on the Van der Windt Group or a cash flow or source and application of funds statement.
5. City Site Estates PLC was censured on 30 October 1997 for its failure, to obtain shareholders' approval and to publish a circular to shareholders prior to completing the disposal of a property representing some 30 per cent of its assets.

If you require any further information, please do not hesitate to contact me.

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APPENDIX TO THE MINUTES OF EVIDENCE

Letter to the Clerk of the Committee from the Office of Mr John Battle MP, Minister of State for Energy and Industry

Further to your letter of 14 April 1999 to Steve Elton in the Office of Science and Technology, I enclose a Memorandum containing the Government's response to the request from the Committee for further information on the regulation of the biotechnology industry, following the Committee's inquiry last Summer and Report on British Biotech.

As discussed with officials, the attached memorandum focuses on the particular interest of the Committee in the issues raised during its inquiry into British Biotech concerning the disclosure of product information in the context of the medicinal and financial regulatory regimes.

The growing importance of biotechnology and the need to ensure the co-ordination of cross-cutting issues has been recognised by the Government through the creation of a new Cabinet Committee on Biotechnology and Genetic Modification (MISC6). One of the first decisions made by the MISC6 was to initiate a thorough review of the broader framework for provision of advice to Government on developments in biotechnology. The aim is to ensure that the Government has in place a system that provides sound advice and proportionate regulation and is at the same time as simple and transparent as possible; that has the flexibility to respond to the fast moving developments in the technology and to public concerns; and that commands the respect of users and the public. Ministers will consider the outcome of this review in parallel with the emerging conclusions of the Government's public consultation on developments in the biosciences. A formal announcement of the outcome is expected shortly.

Memorandum submitted by the Department of Trade and Industry

1. INTRODUCTION

1.1 This memorandum responds to the request of the House of Commons Science and Technology Select Committee (the Committee) to the Department of Trade and Industry (DTI) to submit information in response to the questions set out in its letter of 14 April 1999. The Government understands that the Committee is particularly interested in the issues raised during its inquiry into British Biotech concerning the disclosure of product information in the context of the medicinal and financial regulatory regimes.

1.2 The following responses take the same order as the questions set out in the Committee's letter:

2. *What are the key features of the regulatory regime within which the pharmaceutical biotechnology industry operates?*

2.1 A broad range of legislation, regulations and codes of practice apply to all companies operating in the UK, covering company law, health and safety, employment etc. Of particular interest in the context of the Committee's inquiry are firstly the medicines regulatory regime and secondly the financial regulatory regime.

2.2. The objective of the medicines regulatory regime governing the pharmaceutical industry, including the biotechnology sector, is to safeguard public health by ensuring that all medicines on the UK market meet appropriate standards of safety, quality and efficacy. Safety aspects cover potential or actual harmful effects; quality relates to development and manufacture; and efficacy is a measure of the beneficial effects of the medicine on patients.

2.3 In the UK, the key features by which the Medicines Control Agency (MCA)¹ for human medicines and the Veterinary Medicines Directorate (VMD)² for animal medicines achieve this are:

- a system of licensing before a company can market a medicine;
- monitoring medicines and acting on safety concerns once a company places them on the market;
- checking the standards of pharmaceutical manufacturing and wholesaling; and
- enforcing the requirements of medicines regulation.

The annual reports of the MCA and the VMD give further information about these functions. Copies are placed in the Libraries of both Houses.

¹ An executive agency of the Department of Health.

² An executive agency of the Ministry of Agriculture, Fisheries and Food.

2.4 The European Medicines Evaluation Agency (EMA) carries out analogous functions for approving products for marketing on an EU-wide basis. Under Council Regulation (EEC) 2309/93, it assesses and approves all biotechnology medicinal product applications (although national regulatory agencies remain responsible for approval and monitoring of the safety of clinical trials for all medicinal products, including biotechnology products). The EMA annual report published by the European Commission gives further information about its work. This can be accessed via the Internet. Their address is <http://www.eudra.org>.

2.5 As the Government said in its response³ (the Response) to the Committee's report on British Biotech, the Government is not aware of any conflict between the regulatory regimes governing medicines licensing and those governing disclosure of share-price sensitive information to the financial markets. A company may not issue any advertising material relating to a human medicine in respect of which no marketing authorisation (licence) is in force. However, this does not prevent a company releasing factual information about a product under development to the financial markets if it considers this may be share-price sensitive.

2.6 Secondly, with regard to the financial regulatory regime, all companies are subject to various provisions of the Companies Act 1985 and the financial advertising regime within the Financial Services Act 1986. Unlisted companies are subject to the Public Offer of Securities Regulations 1995. Companies quoted on the London markets are subject to the rules of the London Stock Exchange⁴. The Government understands that the London Stock Exchange is responding to the Committee separately on these requirements.

Have there been any significant changes since the Committee last considered this issue in June and July 1998?

2.7 There have been no significant changes since the Committee last considered the issue in June and July 1998, however a number of amendments have been made to the various medicines regulations over the last 12 months. The MCA and VMD consult the industry on proposals and prepare Regulatory Impact Assessments where appropriate. Recent MCA amendments include changes to the regulations governing the sale and supply of medicines and to those governing the advertising of medicines for human use. This latter amendment [SI 1999/267] aims to clarify existing controls on the advertising of medicines for use under the Medicines (Advertising) Regulations and the Medicines (Monitoring of Advertising) Regulations 1994. The amending Regulations also introduce a procedure for companies to submit written representations against a preliminary decision on advertising to an independent review panel before a final decision is given by Ministers. Nothing in the amendment restricts a company's ability to comply with the Stock Exchange Listing Rules or financial service or company law.

3. Which Government departments have a role in overseeing the regulatory regime? How is activity which crosses departmental boundaries co-ordinated?

3.1 The regulatory regime for quality, safety and efficacy of medicines is the responsibility of the MCA and the VMD. The MCA, an executive agency of the Department of Health, oversees the human medicines regulatory regime and the VMD, an executive agency of the Ministry of Agriculture, Fisheries and Food, does so for animal medicines. Depending on the issue, they co-ordinate medicines regulatory activity across Whitehall as appropriate.

3.2 Treasury is directly responsible for the Public Offer of Securities Regulations 1995 and for associated provisions in Companies Act 1985⁵ and has transferred powers to the Financial Services Authority for the financial advertising regime. The London Stock Exchange has been designated by Treasury as the Competent Authority for public listings.

3.3 As indicated in the Government's Response, the growing importance of biotechnology and the need to ensure the co-ordination of cross-cutting issues has been recognised by the Government through the creation of a new Cabinet Committee on Biotechnology and Genetic Modification. One of the first activities undertaken by the Ministerial Committee has been to initiate a thorough review of the broad regulatory and advisory framework for provision of advice to Government on developments in biotechnology. A formal announcement of the outcome is expected shortly.

³ Submitted on 19 November 1998 in response to the House of Commons Science & Technology Select Committee's Report on British Biotech (HC 888-1).

⁴ Companies listed on the official list are subject to the Listing Rules as laid out by the Competent Authority for listing. Companies quoted on the Alternative Investment Market (AIM) are subject to the AIM Rules.

⁵ The Department of Trade and Industry is responsible for administering the wider provisions of the Companies Acts.

4. *What has been the nature of Government support for our involvement in the development of a code of practice for the industry, currently being formulated by the BioIndustry Association?*

4.1 As indicated in the Government's Response, the Government notes with approval the initiative by the BioIndustry Association (BIA) to develop a Code of Practice for the biotechnology sector. The content of the Code is a matter for the BioIndustry Association. Together with others with an interest in the development of the Code, the Government expects to be consulted shortly by the BIA on a draft of the Code.

5. *The Committee would also welcome any additional comments the Government may wish to make in furtherance of its reply to the Committee's Report on British Biotechnology.*

5.1 Pending the publication of the above Code, the Government has no further comment to make at this stage.

14 May 1999

ISBN 0-10-556534-2



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